IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC DIGOXIN AND DOXYCYCLINE ANTITRUST LITIGATION	**MDL NO. 2724** **16-MD-2724** **HON. CYNTHIA M. RUFE**
THIS DOCUMENT RELATES TO: **ALL DIRECT PURCHASER ACTIONS**	

CERTAIN DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF JOINT MOTION TO DISMISS DIRECT PURCHASER PLAINTIFFS' CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authority

INTRODUCTION

Direct Purchaser Plaintiffs' ("Plaintiffs") Consolidated Amended Class Action Complaint (the "CAC") should be dismissed for two independent reasons. First, Plaintiffs' alleged single conspiracy involving both digoxin and doxycycline hyclate, two different drugs that have nothing in common with each other, makes no sense and therefore is implausible under the standard set by the Supreme Court in *Twombly*. Second, taken separately, Plaintiffs' claims against digoxin sellers and doxycycline sellers do not allege specific facts that suggest that these sellers' conduct was the result of an agreement rather than independent decision-making.

Numerous plaintiffs have blanketed the generic drug industry with dozens of lawsuits claiming that manufacturers of myriad different and distinct generic drugs have conspired to fix the prices of those products. Here, however, Plaintiffs claim the existence of a *single*, over-arching conspiracy to fix the price of both digoxin and doxyxycline.

Yet those drugs are distinct and unrelated, rendering the over-arching conspiracy alleged by Plaintiffs illogical. As alleged in the CAC, digoxin is a heart drug and doxycycline is an antibiotic. Each is used to treat different conditions, prescribed for different patient populations, by different companies, at different prices. Further, the doxycycline referred to in the CAC is actually two separate products: an immediate-release version of doxycycline hyclate and a delayed-release version known as "Doxy DR."

These distinctions matter. A majority of the Defendants—five out of nine— allegedly sold only digoxin or only doxycycline, but not both. Moreover, two of the Defendants that sold doxycycline sold only Doxy DR, but not the immediate-release version of doxycycline. Thus, any claim that there was a single, over-arching conspiracy covering digoxin and both versions of doxycycline is implausible because Defendants have no reason to engage in a conspiracy to fix

prices of products they do not sell, and Plaintiffs can plead no facts to remedy this deficiency. Nor should they be permitted to try.

If Plaintiffs were allowed to proceed with their claim of a single conspiracy, Defendants would not only face the risk of substantial prejudice from conflating evidence concerning digoxin with evidence concerning doxycycline, but Defendants would potentially be jointly and severally liable for alleged conduct related to the pricing of a drug that they did not even sell (and vice versa). To sufficiently plead a single, over-arching conspiracy under Third Circuit law, Plaintiffs must allege actual facts demonstrating a common purpose among Defendants, reliance on each other and continuous cooperation among the otherwise distinct aspects of the alleged conspiracy, and an overlap among Defendants and their activities. Essentially, Plaintiffs must allege facts showing some logical connection or relationship between the alleged fixing of digoxin prices and the alleged fixing of doxycycline prices. They do not even try, and their CAC should be dismissed for this reason alone.

The CAC should also be dismissed because Plaintiffs are unable to state a claim that Defendants engaged in any conspiracy, single or separate, to fix the prices of *either* digoxin or doxycycline individually. Under *Twombly*, they cannot state an antitrust conspiracy claim by merely alleging that Defendants engaged in similar conduct and then asking the Court to infer that the only explanation is a conspiracy, and yet that is exactly what Plaintiffs do here.

The CAC contains no allegations that constitute direct evidence of a conspiracy, and most of the allegations in the CAC do not even relate to digoxin or doxycycline. Those relatively few allegations that do relate to digoxin or doxycycline are insufficient to plausibly suggest that Defendants' actions were the result of an alleged conspiracy as opposed to rational, independent decision-making. The CAC also fails to allege any facts plausibly suggesting that Defendants

engaged in parallel pricing conduct with respect to either product, instead relying on allegations of average aggregate pricing, an approach that has been rejected by the Third Circuit and other courts. Plaintiffs similarly fail to allege the existence of any "plus factors" that would push the alleged conspiracy from merely "possible" to plausible. Instead, Plaintiffs ask the Court to speculate regarding the existence of a specific conspiracy based on general allegations regarding participation in trade association events, a few statements in earnings calls that say nothing about any conspiracy, and the existence of government investigations involving the generic pharmaceutical industry. The Court should decline this invitation and dismiss the CAC on this ground as well.

FACTUAL BACKGROUND

A. The Parties

Plaintiffs are entities that claim to have "directly purchased generic digoxin and doxycycline from one or more of the defendants." CAC ¶¶ 27-30.

Defendants Lannett Company, Inc. ("Lannett"), Impax Laboratories, Inc. ("Impax"), Par Pharmaceutical, Inc. ("Par"), West-Ward Pharmaceuticals Corporation ("West-Ward"), Actavis Holdco U.S., Inc. ("Actavis"), Sun Pharmaceutical Industries, Inc. ("Sun"), Mylan Pharmaceuticals, Inc. ("Mylan"), and Mayne Pharma USA, Inc. ("Mayne")[1] (collectively, "Defendants")[2] are pharmaceutical manufacturers that sell generic drugs in the United States. They sell different pharmaceutical products to a range of direct purchaser customers, including wholesalers, retail drug chains, distributors, and governmental agencies.

[1] The CAC identifies "Mayne Pharma USA, Inc." as a defendant. CAC ¶ 39. That corporate entity does not exist. The proper party is Mayne Pharma, Inc. Mayne's counsel has informed Plaintiffs' counsel of this inaccuracy, and Plaintiffs' counsel has agreed to name the proper Mayne entity in a future filing.

[2] Heritage Pharmaceuticals, Inc., Jeffrey Glazer and Jason Malek are also named as defendants in the CAC, but are not parties to this motion.

Despite Plaintiffs' claims that Defendants engaged in a single, unified conspiracy to fix the prices of two products, generic digoxin and doxycycline,[3] they allege that only four of the nine Defendants sold both drugs. The remaining five Defendants sold only digoxin or doxycycline, but not both. Lannett and Impax manufactured and sold generic digoxin during the Class Period,[4] but not doxycycline. Actavis, Heritage, and Mayne manufactured and sold various doses of generic doxycycline, but not digoxin. Only Par, West-Ward, Sun, and Mylan are alleged to have manufactured and sold both drugs at certain times during the Class Period. Moreover, among Defendants, only Heritage, Mylan, and Mayne sold Doxy DR. CAC ¶¶ 31-39. The following chart shows the products allegedly manufactured and/or sold by each Defendant:

Defendants	**Digoxin**	**Doxycycline**	**Doxy DR[5]**
Lannett	X		
Impax	X		
Actavis		X	
Heritage			X
Mayne			X
Par	X	X	
West-Ward	X	X	
Sun[6]	X	X	
Mylan[7]		X	X

[3] Although the CAC defines "doxycycline" as "generic doxycycline hyclate, including the delayed release ('Doxy DR') version of doxycycline hyclate," in reality, a review of the CAC makes clear that when it comes to doxycycline, regardless of how Plaintiffs define the drug, they are talking about two separate products, doxycycline hyclate and Doxy DR. *See, e.g.*, CAC ¶¶ 96, 98, 105-106, 114. The CAC defines "digoxin" as "doses of generic digoxin taken orally in the form of a tablet or capsule." *See* CAC ¶ 1 n. 1.

[4] The Class Period is defined in the CAC as "October 1, 2012 until the anticompetitive effects of defendants' conduct cease." CAC ¶ 229.

[5] Defendants break out Doxy DR separately on this chart because the CAC actually describes doxycycline hyclate and Doxy DR as two separate products. *See supra* n.2.

[6] Sun is alleged to have been out of the digoxin market until 2015. CAC ¶ 74.

[7] Mylan was out of the digoxin market until sometime in 2015. CAC ¶ 73.

B. The Products Subject To The Alleged Conspiracy

Not only are digoxin and doxycycline made and sold by different Defendants, they each contain different active ingredients and are used to treat different and unrelated medical conditions in different patient populations. There is no overlap in the uses for these drugs—digoxin is a heart drug and doxycycline is an antibiotic.

1. Digoxin: a heart drug

Digoxin is a purified cardiac glycoside derived from the ingredient *digitalis lanata* and is used to treat heart failure and atrial fibrillation. CAC ¶ 66. Plaintiffs allege that various pharmaceutical companies have manufactured generic versions of digoxin, but the number of manufacturers can be hard to quantify at any given time as companies often enter or leave the market; indeed, Plaintiffs themselves are unable to allege the exact number of digoxin manufacturers during the Class Period. *Id.* ¶¶ 69-79, 86 ("During much of the Class Period, there were *at least* three or more separate manufacturers of generic digoxin") (emphasis added).

2. Doxycycline: an antibiotic

In contrast to digoxin, doxycycline is a generic tetracycline antibiotic used to treat bacterial infections including acne, urinary tract infections, eye infections, sexually transmitted diseases, and intestinal infections, among other diseases. *Id.* ¶ 96. It is the generic version of the brand drugs Vibramycin and Vibra-Tabs, developed by Pfizer in 1967 and 1980, respectively. *Id.* ¶ 99. The relevant versions of doxycycline at issue in this case are doxycycline hyclate and Doxy DR. *Id.* ¶ 96. As with digoxin, there have been a large number of generic manufacturers of doxycycline, with "over 20 manufacturers" producing the drug "[a]t one point." *Id.* ¶ 107. Again, Plaintiffs are unable to allege the exact number of doxycycline manufacturers during the Class Period. *Id.* ¶ 112

("At all times during the Class Period, there were at least three or more separate manufacturers of generic doxycycline.").

C. Plaintiffs' Claims

Plaintiffs seek to represent a class of "persons or entities that directly purchased generic digoxin and/or generic doxycycline from defendants in the United States or its territories" during the Class Period. *Id.* ¶ 229. Plaintiffs claim that all Defendants entered into a single conspiracy "to fix, raise, maintain, and stabilize prices at which generic digoxin and generic doxycycline would be sold, allocate markets, and rig bids." *Id.* ¶ 120. Plaintiffs, however, allege no direct evidence of such a conspiracy. Instead, Plaintiffs rely entirely on allegations of what they contend constitute circumstantial evidence of conspiracy.

The alleged circumstantial evidence includes: (1) parallel pricing conduct (although, as explained below, Plaintiffs do not actually allege any parallel conduct at all), (2) attendance at trade association events, (3) statements in earnings calls, and (4) the existence of government investigations. *See, e.g.*, *id.* ¶¶ 7-22, 66-201. Plaintiffs' operative theory, grounded in aggregate rather than actual pricing data, appears to be that Defendants allegedly raised the prices of digoxin and/or doxycycline at or about the same time, and that these price changes *must* have been the result of a conspiracy because of alleged meetings at trade associations, statements made in earnings calls, and existing government investigations. None of Plaintiffs' allegations, however, raises their conspiracy claim beyond the level of pure speculation.

Plaintiffs allege that in mid-October 2013, Lannett and Impax (which Plaintiffs allege were the only market competitors at that time) increased digoxin prices, *id.* ¶¶ 79, 81, though they offer little information about the timing of each company's increase. The only allegation regarding an individual Defendant's digoxin price takes the form of a chart purporting to reflect pricing data for Lannett's 0.25 mg digoxin tablet. *See id.* ¶ 82. But the Lannett data cited by Plaintiffs does not

include actual prices customers paid for digoxin. Compounding this deficiency, Plaintiffs also rely on surveys of average prices (not actual prices) from the National Average Drug Acquisition Cost ("NADAC") that provide no insight into any individual Defendant's digoxin prices.

Plaintiffs then seek to infer illicit communications based on the alleged participation by *some* Defendants in trade association events, including industry dinners and women's initiative events. *See id.* ¶¶ 147-57. Yet the CAC is devoid of any facts regarding what, if anything, was discussed at these gatherings about digoxin or doxycycline.

Plaintiffs also suggest that certain Defendants' statements to market analysts during earnings calls and conferences constitute communications in furtherance of a conspiracy. *Id.* ¶¶ 123-46. However, and even interpreted in the light most favorable to Plaintiffs, the calls reveal no evidence of any back-and-forth communication on pricing, let alone any price-fixing agreement among competitors.

Plaintiffs' doxycycline allegations are just as deficient as their digoxin allegations. Once again, Plaintiffs rely on average instead of actual prices to support their claims. *See id.* ¶¶ 110, 113-14. In fact, Plaintiffs do not make any allegations about Defendants' actual doxycycline prices. They similarly fail to allege any specific communications among Defendants about doxycycline pricing, again trotting out speculative allegations about trade association meetings and other industry events. The allegations pertaining to analyst calls and public statements on doxycycline are no more illuminating, as they reflect nothing more than company executives' offering their views on the market, revenue expectations, and estimates of future business performance. *See id.* ¶¶ 137-46.

Plaintiffs also reference allegations in certain governmental investigations or other lawsuits, including a civil complaint filed in Connecticut federal court by the attorneys general of

several states regarding generic drugs glyburide and doxycycline (the "AG Complaint"). *See id.* ¶¶ 16-19. The AG Complaint, though, does not allege a conspiracy with respect to generic digoxin at all or doxycycline generally, limiting the relevant allegations to Doxy DR. *See State of Conn. v. Aurobindo Pharma USA, Inc.*, No. 3:16-cv-02056-VLB (D. Conn.), Dkt. No. 1 at ¶ 1. The AG Complaint does not name Impax, Lannett, Actavis, Par, West-Ward or Sun as defendants, as those companies have never sold Doxy DR. *See id.*

Finally, Plaintiffs cite to guilty pleas by two former senior executives at Heritage, Jeffrey Glazer and Jason Malek, in response to charges of conspiring to manipulate the prices of Doxy DR and glyburide. CAC. ¶ 20. The government informations charging Glazer and Malek do not disclose facts detailing wrongdoing by any other particular Defendant. Additionally, the conduct involved in those guilty pleas involves only Doxy DR, a drug not manufactured by most of the Defendants in this lawsuit, and glyburide, a drug not at issue here.

ARGUMENT

To survive a motion to dismiss, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). This requires a significant showing, and mere "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" are insufficient. *Twombly*, 550 U.S. at 555. Further, an allegation of a violation of Section 1 of the Sherman Act must do more than create an inference of a possible violation of the Act. *Id.* Even facts that "merely create[] a suspicion [of] a legally cognizable right of action" fall short of the plausibility standard and cannot survive a motion to dismiss. *Id.* (quoting 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216, at 235-36 (3d ed. 2004)).

Instead, a complaint must allege "enough factual matter (taken as true) to suggest that an agreement was made." *Id.* at 556. "Where the well-pleaded facts do not permit the court to infer

more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir. 2009) (quoting *Iqbal*, 556 U.S. at 679). In making this determination, a court should separate "the factual and legal arguments of a claim." *Id*. at 210. While well-pleaded facts must be taken as true, a court "may disregard any legal conclusions." *Id*. at 210-11.

I. Plaintiffs Fail To Plausibly Allege A Single, Unified Conspiracy To Fix The Prices Of Both Digoxin And Doxycycline

The CAC contains only one count alleging that all Defendants engaged in a single conspiracy to "artificially inflate[] the prices of generic digoxin and generic doxycycline." CAC ¶ 247. To determine whether allegations related to disparate facts and events can plausibly state a claim of a single, unified conspiracy, the Third Circuit conducts a "three-step inquiry." *United States v. Kelly*, 892 F.2d 255, 259 (3d Cir. 1989). Under this test, Plaintiffs must allege facts that plausibly show (1) "there was a common goal among the [alleged] conspirators;" (2) the alleged conspirators depended on each other and the "continuous cooperation of the conspirators" to further their common goal; and (3) "the extent to which the participants overlap in the various dealings" that further their common goal. *Id*. Plaintiffs here cannot satisfy any one of these factors because their allegations neither make out a single conspiracy nor provide any basis for believing that such a conspiracy is plausible. It strains reason to conclude that Defendants would be engaged in a price-fixing conspiracy involving drugs they do not make, and drugs that are not therapeutic substitutes for one another.

A. Plaintiffs Fail to Plausibly Allege a Single, Common Goal Among Defendants

Plaintiffs do not plausibly allege a single, common goal among Defendants. *See Kelly*, 892 F.2d at 259. The CAC alleges that Defendants engaged in a single conspiracy to raise the price of *both* generic digoxin *and* generic doxycycline. *See* CAC ¶¶ 3, 5, 229, 235, 247. But Plaintiffs

ignore that there is no overlap in the uses for these drugs, nor do they articulate any reason why some Defendants would engage in a conspiracy to fix the prices of a drug they did not sell.

It is nonsensical to suggest that Defendants could have shared the common goal of fixing the price of both drugs, which are entirely separate products, made from different active ingredients, used for different purposes, prescribed for different patient populations, and sold by different companies at different times. *See In re Optical Disk Drive Antitrust Litig.*, 2011 WL 3894376, No.10-md-2143-RS at *8 (N.D. Cal. Aug. 3, 2011) (dismissing as implausible claim of over-arching conspiracy involving multiple optical disk drive devices and different markets).

According to Plaintiffs, Lannett and Impax sold only digoxin, but not doxycycline, and Actavis, Heritage, and Mayne sold only doxycycline, but not digoxin.[8] How could these defendants have any influence or control over the pricing of drugs they neither manufacture nor sell? And why would they care? Plaintiffs offer nothing to address these fundamental questions. *See In re Auto. Parts Antitrust Litig.*, No. 12-md-02311, 2016 WL 8200512, at *4 (E.D. Mich. Apr. 13, 2016) (denying motion to consolidate claims involving makers of separate component products because complaints "merely advance allegations of separate conspiratorial conduct between different Defendants making different parts"—possibly evidence of separate distinct conspiracies, but not "one, [single] global auto parts conspiracy"). Courts have repeatedly recognized the implausibility of theories like the one Plaintiffs advance here, confirming that it makes no sense that entities could or would conspire to fix prices in markets where they do not compete. *See, e.g.*, *Zachair, Ltd. v. Driggs*, 965 F. Supp. 741, 747 (D. Md. 1997) (dismissing price-fixing claim where plaintiff failed to allege "any facts supportive of an inference that the defendants are competitors"); *United States v. Ashland-Warren, Inc.*, 537 F. Supp. 433, 445 (M.D.

[8] Par did not manufacture both drugs during the operative time period when the conspiracies allegedly were born.

Tenn. 1982) ("Price-fixing by means of bidrigging is flatly impossible when the alleged conspirators are not also competitors."). This Court should reach the same conclusion.

B. Plaintiffs Fail to Plausibly Allege That Defendants Depended on Each Other or Were Engaged in Continuous Cooperation

Plaintiffs also plead no facts suggesting that the alleged single conspiracy required the Defendants—including those that only manufactured or sold one of the drugs—to depend on each other or engage in "continuous cooperation" in order to succeed. *See Kelly*, 892 F.2d at 259. "To evaluate interdependence, the court engages in an inquiry focused on the extent to which the success or failure of one conspiracy is independent of a corresponding success or failure by the other." *In re K-Dur Antitrust Litig.*, No. 01-cv-1652-SRC-CLW, 2016 WL 755623, at *21 (D.N.J. Feb. 25, 2016); *see also In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 332 (3d Cir. 2010) ("evidence [must] clearly indicate[] that the defendants would not have undertaken their common action without reasonable assurances that all would act in concert.").

Here, no allegations in the CAC plausibly suggest reliance or continuous cooperation among the various Defendants. Nothing is said about how the price of one drug impacts the other, what the supply and demand for digoxin does to supply and demand for doxycycline, or why a particular digoxin defendant would benefit from the actions of a doxycycline defendant. Instead, Plaintiffs summarily allege that Defendants "conspired, combined, and contracted to fix, raise, maintain, and stabilize prices," CAC ¶ 120, and that Defendants came to a "meeting of the minds" through their participation in trade association events. *Id.* ¶ 158. Plaintiffs also use unsupported suggestions that "various" albeit "unknown" co-conspirators "have willingly conspired with defendants in their unlawful conduct." *Id.* ¶¶ 41-43. But nowhere do Plaintiffs explain how the alleged fixing of digoxin prices depended on the alleged fixing of doxycycline prices, or vice versa. This omission is fatal.

C. Plaintiffs Fail to Plausibly Allege Sufficient Overlap Among Defendants

Plaintiffs similarly fail to allege facts that plausibly suggest sufficient overlap among the various Defendants and their conduct. *See Kelly*, 898 F.2d at 259. This factor focuses on whether there is evidence of concerted action in furthering the goals of the conspiracy among the participants. *Id.* at 260. "While it is not necessary that every defendant participate in every transaction, the mere overlap of some of the defendants in some of the transactions is, on its own, insufficient to establish an overarching agreement." *Dahl v. Bain Capital Partners, LLC*, 937 F. Supp. 2d 119, 135 (D. Mass. 2013) (internal citations omitted). Here again, there is no plausible suggestion that a particular digoxin manufacturer coordinated with a doxycycline manufacturer to increase doxycycline profits or vice versa. *See Kelly*, 898 F.2d at 260. Instead, Plaintiffs allege different companies selling different products to treat different conditions. Those allegations compel only one conclusion: there is no overlap.

D. Plaintiffs Should Not Be Permitted to Proceed on Their Claim of a Single Conspiracy Because It Would Result in Undue Prejudice to Defendants

Plaintiffs' inability to adequately plead a single conspiracy is not a mere technical pleading defect. Allowing Plaintiffs to proceed on a single conspiracy claim involving separate Defendants and products with little to no overlap would expose Defendants to substantial undue prejudice. *See In re Auto. Parts*, 2016 WL 8200512, at *2 (stating it would be prejudicial to consolidate separate conspiracy claims into single, over-arching conspiracy claim given differences among defendants in individual alleged conspiracies). For example, digoxin-only Defendants should not be jointly and severally liable for injuries allegedly arising from sales of doxycycline, and vice versa. Defendants have no control over pricing of products they neither manufacture nor sell, and should not face potential liability for actions outside their control. Allowing the case to proceed on a theory of single conspiracy would expose Defendants to precisely that type of liability. *Cole's*

Wexford Hotel, Inc. v. UPMC, 127 F. Supp. 3d 387, 414–15 (W.D. Pa. 2015) (explaining antitrust liability is joint and several and each co-conspirator "is liable for the entire amount of damages caused by the violation regardless of the degree of its culpability in causing the damages").

* * * * *

In short, Plaintiffs should not be permitted to proceed with a single, over-arching conspiracy pertaining to digoxin and doxycycline, and the Court should dismiss the CAC on this ground alone.

II. Plaintiffs Fail To State A Plausible Claim That Defendants Conspired To Fix Prices Or Allocate Markets For Digoxin

Even if Plaintiffs had pleaded a separate digoxin conspiracy, their claims would still fail as a matter of law under *Twombly* because there are no factual allegations regarding digoxin that plausibly imply collusion. In a case alleging a violation of Section 1 of the Sherman Act, the "crucial question" is "whether the challenged anticompetitive conduct stems from independent decision or from an agreement." *Twombly*, 550 U.S. at 553 (citations and internal quotations omitted); *see also Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011) ("Unilateral action, regardless of motivation, is not a violation of Section 1."). Indeed, because similar business conduct among various competitors may be just as consistent with a conspiracy as with rational, competitive and unilateral business strategy, a plaintiff can survive a motion to dismiss only by identifying and pleading facts that are "suggestive enough to render a § 1 conspiracy *plausible*." *Twombly*, 550 U.S. at 556 (emphasis added).

Under *Twombly* and its progeny, a plaintiff cannot escape dismissal by alleging similar conduct among the defendants and asking the court to infer that the *only* explanation is a conspiracy. *See Finkelman v. Nat'l Football League*, 810 F.3d 187, 201 (3d Cir. 2016) (explaining plaintiffs in *Twombly* "looked around and saw conduct *consistent* with conspiracy,

but [alleged] no facts that indicated more plausibly that a conspiracy actually existed.") (emphasis in original). Instead, the complaint must "delineate[] to some sufficiently specific degree" that each defendant "purposefully joined and participated in the conspiracy." *In re Processed Egg Prods. Antitrust Litig.*, 821 F. Supp. 2d 709, 720 (E.D. Pa. 2011).

The CAC falls far short of this standard: Plaintiffs' allegations fail to suggest that the alleged digoxin price increases were the product of collusion as opposed to the individual Defendants' unilateral decision-making and independent assessments of each market.

A. Plaintiffs Do Not Sufficiently Allege a Digoxin Conspiracy

1. Plaintiffs do not allege direct evidence of an agreement to fix prices or allocate customers for digoxin

To plead a plausible conspiracy, plaintiffs must allege facts that constitute either direct or circumstantial evidence of a conspiracy. *Burtch*, 662 F.3d at 225. "Direct evidence of a conspiracy is evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted." *Id.* The "paradigmatic example" of such evidence is a "recorded phone call" featuring an agreement to fix prices. *Mayor and City Council of Baltimore, Md. v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013); *see also InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 162-63 (3d Cir. 2003) (providing examples of direct evidence such as "a memorandum produced by a defendant conspirator detailing the discussions from a meeting of a group of alleged conspirators"). The CAC here contains nothing of the sort.

Indeed, there are no specific allegations regarding when Defendants met or communicated to form the supposed digoxin conspiracy, which of Defendants' employees were involved, or even what the contours of any alleged agreement were. *Cf. Twombly*, 550 U.S. at 591 n.10; *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 602 F.3d 237, 255 (3d Cir. 2010); *see also Great W. Mining & Mineral Co. v. Fox Rothschild LLP*, 615 F.3d 159, 179 (3d Cir. 2010) (affirming

dismissal, explaining: "Applying *Twombly*, [a] statement that Defendants engaged in a concerted action of a kind not likely to occur in the absence of agreement is inadequate to properly plead an agreement."). In *Burtch*, for example, the Third Circuit found direct evidence lacking where the complaint cited telephone calls, but did not "specify a time or place that any actual agreement to fix credit terms occurred, nor . . . indicates that any particular individuals or Factors made such an agreement." Nothing in the CAC comes close to meeting that standard.

Instead, Plaintiffs allege an agreement to fix digoxin prices in only the most conclusory of terms. For example, the CAC alleges, in boilerplate language, that "defendants entered into agreements with one another on the pricing and/or allocation of markets for generic digoxin . . . ." CAC ¶ 245. However, such allegations of a "conclusory nature . . . are not entitled to assumptions of truth," *Burtch*, 662 F.3d at 225, and *Twombly* requires more than "a few stray statements [that] speak directly of agreement." 550 U.S. at 564. *See also Schuylkill Health Sys. v. Cardinal Health 200, LLC*, No. 12-cv-7065, 2014 WL 3746817, at *7 (E.D. Pa. July 30, 2014) (dismissing conspiracy claims, explaining "most telling factor" was that plaintiff "state[d] only in a conclusory fashion that Defendants conspired to allocate markets or employ identical contract terms"). Further, the CAC lacks *any* allegation related to Defendants' purported "allocation of markets for generic digoxin." CAC ¶ 245. Accordingly, Plaintiffs fail to plead a digoxin conspiracy through allegations of direct evidence.

2. Plaintiffs do not sufficiently plead circumstantial evidence of a digoxin conspiracy

Plaintiffs also fail to plead an actionable digoxin conspiracy through circumstantial evidence. The CAC does not sufficiently allege either Defendants' parallel conduct or the requisite "plus factors" that reveal "circumstances under which . . . the inference of rational independent choice [is] less attractive than that of concerted action." *Lum v. Bank of Am.*, 361 F.3d 217, 230

(3d Cir. 2004); *see also In re Chocolate Confectionary Antitrust Litig.*, 999 F. Supp. 2d 777, 786 (M.D. Pa. 2014) ("Specifically, in a parallel plus case, plaintiffs must prove not only that the defendants' behavior was 'consciously parallel'—that is, that each was aware of the others' conduct and this awareness was an element in their decision making process—but also 'certain plus factors.'"), *aff'd*, 801 F.3d 383 (3d Cir. 2015). Plaintiffs' claims fail—and should be dismissed—for this reason as well.

a. Plaintiffs cannot plead parallel conduct through allegations regarding the average market price of digoxin.

Given the nature of Plaintiffs' claims, the CAC is strikingly bereft of allegations regarding the prices each Defendant charged for digoxin during the Class Period. Plaintiffs do not attempt to show that each digoxin manufacturer was charging the same price for any dosage of digoxin or increased digoxin prices in parallel, a fatal omission requiring dismissal as a matter of law. *See, e.g., Resco Prods., Inc. v. Bosai Minerals Group Co.*, 158 F. Supp. 3d 406, 424 (W.D. Pa. 2016).

The CAC is even unclear as to exactly what "price" Defendants allegedly fixed, for example, whether it was a list price or the actual transactional price Defendants charged to customers. The lack of specificity is startling given that Plaintiffs claim to have purchased digoxin directly from Defendant sellers. *See* CAC ¶¶ 27-30. Indeed, Plaintiffs' only allegation regarding any individual Defendant's digoxin prices comes in a chart supposedly reflecting certain pricing data for Lannett's 0.25 mg digoxin tablet. *See* CAC ¶ 82. This chart, purportedly "borrowed" from a report prepared by Dr. Stephen Schondelmeyer, does not indicate what Lannett's customers *actually* paid for digoxin. Instead, it lists figures for Average Wholesale Price ("AWP") and Wholesale Acquisition Cost ("WAC"), as well as a data point labeled "Retail $/Day." *Id.*

Plaintiffs acknowledge that AWP and WAC are only "benchmark prices," and Dr. Schondelmeyer's report explains that the "Retail $/Day" figure is (1) not entirely accurate, and (2)

has nothing to do with the prices Lannett actually charged. Specifically, he notes that the figure "may or may not reflect what the [Pharmacy Benefit Manager] paid the pharmacy or the usual and customary price." Ex. A, Schondelmeyer Rpt. at 7 (emphasis added).[9] In other words, the chart says absolutely nothing about either Lannett's actual transaction prices or the prices charged by other digoxin sellers.[10]

Lacking allegations regarding each individual Defendant's prices, Plaintiffs instead rely exclusively on trends in the *average* market-wide price for the .125 mg digoxin tablet (not the 0.25 mg tablet) compiled from a survey of pharmacies and reported in the NADAC list (prices pharmacies paid wholesalers, not the prices charged by Defendants to their customers). *See* CAC ¶ 85. Plaintiffs do not allege that the NADAC list[11] shows the prices individual manufacturers charged or when any individual Defendant increased its price for the .125 mg digoxin tablet.[12] Nor do Plaintiffs allege which Defendants sold the .125 mg tablet. "Average prices" in the NADAC list, therefore, say nothing about what any given Defendant actually charged, whether and when

[9] "[A]lthough a district court may not consider matters extraneous to the pleadings, a document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." *U.S. Express Lines, LTD. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002) (internal quotation marks and citation omitted); *see also Hynoski v. Columbia Cty. Redevelop. Auth.*, 941 F. Supp. 2d 547, 555 (M.D. Pa. 2013) ("The court may . . . take judicial notice of certain facts, as well as undisputedly authentic documents if the complainant's claims are based upon these documents."). Because Plaintiffs specifically rely on the Schondelmeyer report in the CAC, the Court may properly consider the full contents of the report on this motion to dismiss.

[10] The CAC also does not allege that each Defendant manufactured and sold a 0.25 mg digoxin tablet, further demonstrating the irrelevance of Dr. Schondelmeyer's chart.

[11] *See* Ex. B, NADAC Methodology at 10. The Court may take judicial notice of the NADAC methodology, which is published by the Center for Medicare and Medicaid Services and available at Medicaid.gov. *See, e.g., Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 165 (S.D.N.Y. 2015) (finding it "clearly proper to take judicial notice" of "documents retrieved from official government websites. . .[including] Medicare.gov").

[12] The NADAC methodology explains that the NADAC data cannot be used to show individual generic drug manufacturer's prices. Ex. B, NADAC Methodology at 15 ("one generic drug NADAC will apply to all [manufacturers] within a drug grouping"). The methodology also demonstrates that the average pricing data masks price differentials in different ways, for example, by failing to reflect regional price variations or differences in independent or chain pharmacies. *Id.*

any Defendant raised its prices, and the timing of any responses by other Defendants. The NADAC list simply fails to show parallel conduct.

The Third Circuit has rejected Plaintiffs' attempted use of average prices, explaining that the Court does "not believe that trend lines of *average prices* are a reliable indicator of transactional prices." *In re Baby Food Antitrust Litig.*, 166 F.3d 112, 129 (3d Cir. 1999) (emphasis in original). As a result, courts have dismissed price-fixing claims where (as here) plaintiff offers only changes in the *average* market price of the allegedly fixed product. *See Resco Prods.*, 158 F. Supp. 3d at 424 (holding plaintiff failed to demonstrate parallel pricing where it asserted that defendants' prices "doubled during 2003 and 2004 and increased an additional 70 [percent] between 2004 and 2007" because general price movements could not demonstrate parallel increases absent evidence "of the amount or timing of any of the price increases it claim[ed] were the product of collusion."); *see also In re Musical Instruments and Equip. Antitrust Litig.*, 798 F.3d 1186, 1197 (9th Cir. 2015) (affirming dismissal because average prices did not demonstrate whether prices charged by defendants actually increased); *Oliver v. SD-3C LLC*, No. 11-01260, 2016 WL 5950345 at *5-12 (N.D. Cal. Sept. 30, 2016) (dismissing amended complaint and rejecting use of price charts to establish parallel conduct).

Moreover, the NADAC average price data on which Plaintiffs rely actually *contradicts* their digoxin conspiracy theory. Plaintiffs allege that the initial (and indeed only significant) increase in the average market price of digoxin occurred in October 2013—before Plaintiffs allege that the other Defendants were selling digoxin. *See* CAC ¶¶ 84-85. Plaintiffs suggest that Lannett increased its price during this time period, *id.* ¶¶ 81-82, 93, but provide no other specific allegations of pricing by other Defendants. Plaintiffs acknowledge that Par and Mylan were not selling digoxin in 2013, and also recognize that West-Ward was not selling product at the time of the 2013

price increase.[13] *Id.* ¶¶ 73-75, 81. And although Plaintiffs suggest that the subsequent entry by Par and Mylan into the market is somehow consistent with their alleged conspiracy, their NADAC chart shows just the opposite: prices steadily decreased after each manufacturer's entry. Indeed, Plaintiffs plead a high average market price of $1.08 per .125 mg digoxin tablet in January 2014, just before Par's alleged entry, and the NADAC data shows that the average price began to trend downward thereafter. In fact, prices fell to less than $0.80 per tablet by the end of 2015. *Id.* ¶¶ 83, 85. If the NADAC data is to be given any weight, it reflects nothing more than a functioning competitive market where price increases invite entry by new competitors, which, in turn, creates downward pressure on prices. *Cf. id.* ¶ 87 ("As long as manufacturers continue to enter the market, generic drug prices continue the general downward trend.").

At bottom, the NADAC average price information cannot serve as a surrogate for the factual allegations necessary to allege parallel digoxin prices, nor can it create an inference that the digoxin market exhibited anticompetitive behavior. Accordingly, Plaintiffs fail to plead the "parallel" part of their "parallel plus" digoxin conspiracy, and their claim must be dismissed.[14]

[13] Plaintiffs allege that West-Ward ceased digoxin production due to facility issues "in the beginning of 2013." CAC ¶ 75. Although Plaintiffs assert that West-Ward resumed manufacturing digoxin tablets in July 2013, they allege in the same breath that West-Ward was not in the digoxin market during the initial "mid-October 2013" price increase and only increased prices "when it re-entered." *Id.* ¶ 81. That same allegation makes no reference to Sun's re-entry into the digoxin market. *Id.* Moreover, Plaintiffs' own allegations, while inconsistent and contradictory at times, state that "Sun began selling digoxin in or around April 2015." *Id.* ¶ 74. This is borne out further by the Lannett 2014 Q1 earnings call Plaintiffs cite and rely on, *see, e.g., id.* ¶¶ 126-27, in which Lannett's CEO stated the company was "only 1 of 2 people in the market" (the other being Impax) and that "some of the other competitors may come back into the market." Ex. C, November 7, 2013 Lannett Earnings Call Transcript, at p. 8 (emphasis added).

[14] Plaintiffs do not allege any facts regarding an agreement to allocate the digoxin market. Plaintiffs thus fail to demonstrate that Defendants acted similarly, let alone in parallel, regarding whether to bid for or otherwise seek business from customers.

b. Plaintiffs do not plead sufficient "plus factors" to create an inference of conspiracy.

Even if Plaintiffs adequately plead parallel conduct (and they do not), their digoxin conspiracy claim still fails as a matter of law because they fail to allege any facts plausibly suggesting that such conduct was the product of collusion. Without sufficient allegations of plus factors, an allegation of parallel conduct "stops short of the line between possibility and plausibility." *Twombly*, 550 U.S. at 557; *see also In re Musical Instruments,* 798 F.3d at 1194 (citing *Twombly* and holding plaintiff must allege factual allegations that are "largely inconsistent with unilateral conduct [and] largely consistent with explicitly coordinated action").

The Third Circuit has identified three potentially relevant plus factors: "(1) evidence that the defendant had a motive to enter into a price fixing conspiracy; (2) evidence that the defendant acted contrary to its interests; and (3) evidence implying a traditional conspiracy." *In re Ins. Brokerage*, 618 F.3d at 321-22. The first two plus factors, however, "are not especially helpful in price-fixing cases where, as here, there are [alleged] parallel price increases by competitors in a concentrated market." *Superior Offshore Int'l, Inc. v. Bristow Group, Inc.*, 490 F. App'x 492, 499 (3d Cir. 2012); *see* CAC ¶ 203. This is because "the first two factors largely restate the phenomenon of interdependence." *In re Chocolate Confectionary Antitrust Litig.*, 801 F.3d 383, 398 (3d Cir. 2015) (citing *In re Baby Food*). Such allegations, therefore, are not alone sufficient to state a plausible price-fixing conspiracy claim. Instead, because Plaintiffs allege that Defendants are "oligopolists" in a concentrated market, CAC ¶ 211, Plaintiffs need to establish their claim through evidence implying the existence of a traditional conspiracy, which they fail to do. Regardless, none of Plaintiffs' proffered plus factors holds up to scrutiny.

(1) There are no allegations of motive or actions against self-interest.

Plaintiffs' allegations regarding Defendants' motive to enter a digoxin conspiracy are both unremarkable and insufficient as a plus factor. Plaintiffs plead only that "increased revenue and higher profits . . . [were] a motive for the conspiracy." CAC ¶ 162. That motive exists in every industry and, taken to its logical conclusion, Plaintiffs' position would make the plus factor of motive a nullity. *See Hyland v. HomeServices of Am., Inc.*, 771 F.3d 310, 321 (6th Cir. 2014) ("If this Court were to find that Defendants' motive to maximize profits supported an inference of an illegal conspiracy, then all businesses would be subject to antitrust liability."). And, indeed, the Third Circuit has been clear that a desire to increase profits through price increases does not imply the existence of a conspiracy. *See In re Baby Food*, 166 F.3d at 134-35 ("Profit is a legitimate motive in pricing decisions, and something more is required before a court can conclude that competitors conspired to fix pricing in violation of the Sherman Act.").

Nor does engaging in conscious parallelism lead to the conclusion that Defendants were acting against their self-interest. As the Third Circuit has explained, while conscious parallelism is "a common reaction of 'firms in a concentrated market [that] recognize their shared economic interests and their interdependence with respect to price and output decisions,'" this behavior "does not suffice as an agreement under Section 1." *Burtch*, 662 F.3d at 226-27.

Indeed, courts routinely recognize that "[a]n action that would seem against self-interest in a competitive market may just as well reflect market interdependence giving rise to conscious parallelism." *In re Musical Instruments*, 798 F.3d at 1195. Thus, courts have held that "[t]here is nothing irrational or self-defeating about the alleged parallel pricing in an oligopolistic market in which enlightened economic actors may independently and unilaterally choose to adopt and maintain supra-competitive pricing." *Superior Offshore Int'l*, 738 F. Supp. 2d at 515 (dismissing

claim where "Plaintiff's only allegations of acts against each Defendant's economic self-interest are allegations of Defendants' parallel price increases during a period of decreased demand"); *see also Twombly*, 550 U.S. at 554 ("The inadequacy of showing parallel conduct or interdependence, without more, mirrors the ambiguity of the behavior: consistent with conspiracy, but just as much in line with a wide swath of rational and competitive business strategy unilaterally prompted by common perceptions of the market.").

Nor can Plaintiffs establish a common motive through conclusory and general allegations that the digoxin market is "susceptible to collusion." CAC ¶ 202. Even reading Plaintiffs' market structure allegations in the most generous light, they remain insufficient to show that Defendants formed an agreement regarding digoxin. *See, e.g., Schuylkill Health*, 2014 WL 3746817 at *7 ("even assuming the . . . market is susceptible to collusion given high barriers to entry and large fixed costs of production, this factor alone does not support SHS's conspiracy claim"). In fact, many of Plaintiffs' allegations are *inconsistent* with any claim that the digoxin market was susceptible to collusion. For example, Plaintiffs allege that numerous companies entered the market during the alleged conspiracy period, which, as reflected in Plaintiffs' NADAC chart, drove prices down. This outcome is the antithesis of collusion.

Plaintiffs' allegations that it was against each Defendant's unilateral self-interest to increase prices and potentially lose sales and market share fare no better. Courts have found such allegations insufficient to establish a plus factor indicating that a conspiracy is more plausible than independent conduct. *See, e.g., In re Chocolate Confectionary*, 801 F.3d at 401 ("Deciding not to follow a price increase initiated by a rival is just one rational response that an oligopolist can take, a fact acknowledged by economists"); *In re Baby Food*, 166 F.3d at 135 ("[E]vidence of action that is against self-interest . . . must be so unusual that in the absence of an advance agreement, no

reasonable firm would have engaged in it."). As the Ninth Circuit explained in *In re Musical Instruments,* "so long as prices can be easily readjusted without persistent negative consequences, one firm can risk being the first to raise prices, confident that if its original price *is* followed, all firms will benefit." 798 F.3d at 1195 (emphasis in original); *see also Mayor and City Council of Baltimore*, 709 F.3d at 139-40 ("a common reaction of firms in a concentrated market [is to] recognize their shared economic interests and their interdependence with respect to price and output decisions," but "[s]uch 'conscious parallelism,' however, is not unlawful in itself."). This well-accepted economic principle demonstrates why, in a concentrated industry like the one alleged here, follow-the-leader pricing (to the extent it occurs) is both rational and not indicative of collusion.

In any event, "[a]s a general rule, evidence that a market is ripe for collusion, that defendants acted against their interests, or that defendants were motivated to collude is too ambiguous to support an inference of agreement, because these circumstances could just as readily be the result of unilateral independent conduct." *In re Chocolate Confectionary*, 999 F. Supp. 2d at 789 (citing *Baby Food,* 166 F.3d at 122). Plaintiffs do not plead any facts that are more consistent with a conspiracy to fix digoxin prices than with each Defendant's unilaterally deciding to set its individual prices in an attempt to maximize profits. Thus, the allegations are insufficient to establish this plus factor as a matter of law.

(2) Plaintiffs do not allege any "traditional" evidence of a conspiracy.

The CAC likewise fails to allege facts evidencing a traditional conspiracy as it includes nothing to suggest "that the defendants got together and exchanged assurances of common action or otherwise adopted a common plan" regarding price-fixing or market allocation with respect to digoxin. *Superior Offshore Int'l,* 490 Fed. App'x at 499. Rather, Plaintiffs attempt to cobble

together a conspiracy claim from allegations of (1) government investigations into the generic drug industry, (2) Defendants' participation in a trade association and general industry functions, and (3) unilateral public statements made during earnings calls and in investor reports. These allegations are not sufficiently tailored to digoxin and are incapable, in any event, of creating an inference of a digoxin conspiracy as a matter of law.

(a) Government investigations are not a plus factor here.

Plaintiffs rely heavily on broad allegations regarding government investigations and court filings, but these allegations do nothing to tie Defendants' alleged conduct regarding digoxin to any collusion or illicit agreement.

Plaintiffs' allegations that the DOJ is investigating certain Defendants, for example, do not imply a conspiracy related to digoxin because those allegations do not make an unlawful agreement any more plausible than independent conduct. Indeed, courts have rejected similar attempts to state a Section 1 claim by relying on the existence of a DOJ grand jury investigation. In *Superior Offshore Int'l,* Judge Legrome Davis considered this very issue in granting the defendants' motion to dismiss. *See Superior Offshore Int'l Inc. v. Bristow Group, Inc.*, 738 F. Supp. 2d 505, 508 (D. Del. 2000), *aff'd*, 490 F. App'x 492 (3d Cir. 2012). The complaint in that case included allegations that the defendants had received DOJ subpoenas in connection with a pending grand jury investigation. *Id*. Even though the subpoenas were purportedly related to the alleged conduct underlying the civil suit, the court concluded that the allegations of the existence of a government investigation did not "bolster" the plaintiff's conspiracy theory:

> [The subpoenas and investigation] do not permit a reasonable inference that any Defendant committed an antitrust violation *because proof of the mere occurrence of the DOJ's investigation is equally consistent with Defendants' innocence*. . . . Thus, the initiation of the DOJ's investigation and Defendants' receipt of document subpoenas. . . . do not enhance the plausibility of

> Plaintiff's claim and do not warrant subjecting Defendants to the burdens of antitrust discovery.

Id. at 516-17 (emphasis added); *see also In re Graphics Processing Units Antitrust Litig*., 527 F. Supp. 2d 1011, 1024 (N.D. Cal. 2007) ("The [DOJ] investigation . . . , however, carries no weight in pleading an antitrust conspiracy claim. It is unknown whether the investigation will result in indictments or nothing at all."); *LaFlamme v. Societe Air France*, 702 F. Supp. 2d 136, 154 (E.D.N.Y. 2010) (dismissing Section 1 claim and holding that "neither mere participation in an investigatory interview nor the receipt of a subpoena is necessarily probative of conspiracy"); *Hinds Co. Miss. v. Wachovia Bank, N.A.*, 620 F. Supp. 2d 499, 514 (S.D.N.Y. 2009) ("This Court agrees that the various investigations, inquiries, and subpoenas do not make the CAC's allegations plausible"); *In re Tableware Antitrust Litig*., 363 F. Supp. 2d 1203, 1205 (N.D. Cal. 2005) (rejecting reliance on Attorney General investigation because otherwise "mere knowledge of a governmental investigation would suffice—without any further inquiry on a would-be plaintiff's part—to expose the targets of such investigations to free-ranging civil discovery.").

Further, although Plaintiffs invoke the recent guilty pleas of two former Heritage executives (Jeffrey Glazer and Jason Malek), *see* CAC ¶¶ 14-15, 193, it is undisputed that Heritage has *never* manufactured digoxin. While Heritage may have sold Doxy DR (an entirely different product), Plaintiffs cannot adequately plead a conspiracy regarding digoxin through circumstantial evidence of an alleged conspiracy to fix the price of Doxy DR absent specific allegations of factual linkage—allegations that are wholly absent here. *See In re Chocolate Confectionary*, 801 F.3d at 403 (holding plaintiffs must show that relevant activities in respective markets "are sufficiently linked or tied in some way, e.g., the people involved in the conspiracies are the same or overlapping"); *see also In re London Silver Fixing, Ltd*., No. 14-MD-2573 (VEC), 2016 WL 5794777 at *14 (S.D.N.Y. Oct. 3, 2016) (holding evidence of defendants' conduct with respect to

one metal market had no bearing on antitrust claims concerning different market). Plaintiffs cannot, and do not, link Malek, Glazer, and, more broadly, Heritage, to any alleged conspiracy concerning digoxin.[15]

For this same reason, the AG Complaint, *see* CAC ¶¶ 195-96, does not support Plaintiffs' allegations of a digoxin-related conspiracy. Digoxin is not mentioned anywhere in the AG Complaint. Moreover, as Plaintiffs characterize it, the AG Complaint alleges that Heritage was "[t]he principal architect and ringleader of the conspiracies." *Id.* ¶ 199. Again, Plaintiffs do no (and cannot) claim that Heritage ever participated in the digoxin market, so these allegations are irrelevant.

Nor, finally, does the Congressional probe "relating to the escalating prices of generic pharmaceuticals," *id.* ¶ 173, imply collusion with respect to digoxin. Plaintiffs do not allege that Congress was investigating price-fixing or market allocation regarding digoxin or any other drug. And Defendants are not aware of a single reported decision in which a Congressional investigation was found to provide circumstantial evidence of an antitrust conspiracy. *Cf. Persian Gulf Inc. v. BP W. Coast Prods. LLC*, No. 15-cv-01749-L-BGS, 2016 WL 4574357 at *17-19 (S.D. Cal. July 14, 2016) (dismissing conspiracy claim and holding "U.S. Senators' request to investigate the gasoline price spikes also does not necessarily suggest a collusive agreement"). Accordingly, Plaintiffs' allegations regarding government investigations and inquiries do not amount to traditional conspiracy evidence.

[15] Further, Plaintiffs fail to link their vague allegations regarding a "leniency applicant" to the specific drugs alleged here. *See* CAC ¶ 200. They do not even allege whether any Defendant in this action is the alleged applicant or what drugs are included in the leniency application.

(b) The trade association allegations are also insufficient.

Plaintiffs' allegations regarding Defendants' participation in and attendance at GPhA meetings and other industry functions similarly do not constitute a plus factor. In the Third Circuit, it is "canon that evidence of competitors meeting together, without more, is insufficient to raise inferences of conspiracy without additional evidence." *In re Domestic Drywall Antitrust Litig.*, 163 F. Supp. 3d 175, 197 (E.D. Pa. 2016); *see also Twombly*, 550 U.S. at 567 n.12 (rejecting notion that defendant should be forced to "devote financial and human capital to hire lawyers, prepare for depositions, and otherwise fend off allegations of conspiracy[,] all this just because he belonged to the same trade guild as one of his competitors"); *In re Chocolate Confectionary*, 999 F. Supp. 2d at 804 ("The court rejects the suggestion that the contemporaneous presence of defendants' officers at a trade association meeting permits an inference of conspiracy."); *Superior Offshore, Int'l*, 738 F. Supp. 2d at 516 ("Plaintiff's allegations concerning Defendants' opportunities to conspire" at trade association meetings "do not permit a reasonable inference of collusion"); *Resco Prods.*, 158 F. Supp. 3d at 425-26 (holding it "is not reasonable" to infer conspiracy from trade association membership); *see also Just New Homes, Inc. v. Beazer Homes*, 293 F. App'x 931, 934 (3d Cir. 2008) ("Membership in a trade association, without more, does not violate the antitrust laws.").

Courts consistently reject attempts such as those made by Plaintiffs here to insinuate that there is something sinister about routine attendance at industry trade association meetings. *See Schuykill Health*, 2014 WL 3746817 at *7 ("The fact that the Defendants are members of a trade association that hosts annual conferences does not transform Defendants' parallel conduct into a conspiracy."); *see also Bookhouse of Stuyvesant Plaza, Inc. v. Amazon.com, Inc.*, 985 F. Supp. 2d 612, 618 (S.D.N.Y. 2013) (dismissing complaint because plaintiffs' failure to "specify who

participated in these hypothetical discussions or agreements. . . . falls well short of the line between possibility and plausibility of entitlement to relief").

The CAC does not link any of these meetings or functions to any agreement to fix digoxin prices. As a result, these allegations, even taken as true, demonstrate merely that Defendants may have had the *opportunity* to conspire, but they do not support an inference of actual conspiracy. *See, e.g.*, CAC ¶ 155 ("At these meetings and trade shows, generic pharmaceutical manufacturers have *opportunities* to discuss and share competitively sensitive information") (emphasis added); ¶ 213 ("Certain defendants are members of trade association GPhA which provides and promotes *opportunities* to communicate") (emphasis added).

In fact, many of Plaintiffs' allegations on this point are inconsistent with any alleged conspiracy. For example, although Plaintiffs allege seven meetings of the GPhA, *see id.* ¶ 154, these allegations belie any inference that the meetings were a conduit to fix prices or allocate customers in the digoxin market. Lannett is only alleged to have attended two of the first five such meetings, and was notably absent from the February 2014 GPhA Annual Meeting, which would have been just a few months into the purported digoxin conspiracy. *Id.* Meanwhile, West-Ward is not alleged to have attended any GPhA meeting until late October 2014.[16] And the only trade association meeting which both Lannett and Impax allegedly attended was a "Technical Conference" in October 2012, *more than a year before* the claimed October 2013 price increase that is the focus of this suit. *See* CAC ¶ 154.

Plaintiffs allege that these meetings took place, but they do not allege that there was any actual discussion of digoxin prices, customers, or market conditions at any of these meetings. They

[16] Although Plaintiffs allege that Par and Mylan attended each of these meetings, they were not in the digoxin market until, respectively, early 2014 and 2015. Likewise, Sun was not in the market until April 2015, so its alleged attendance at some of the earlier meetings cannot be related to a purported digoxin conspiracy.

do not allege that any employee of any Defendant with responsibility for digoxin pricing or sales attended any of these meetings. They do not allege that any meetings attended by digoxin manufacturers were closed to other members of the GPhA, although they acknowledge that membership extends to distributors, chemical manufacturers, and suppliers of other goods and services in the industry. *See* CAC ¶ 149. *Cf. In re Text Messaging Antitrust Litig.*, 782 F.3d 867, 878 (7th Cir. 2015) (rejecting inference of conspiracy from trade association meetings in part because "representatives of companies not alleged to be part of the conspiracy frequently were present at these meetings" which eliminated probability of collusion). Given these allegations (or lack thereof), Plaintiffs' suggestion that the GPhA served as a conduit for collusion is unsupportable and implausible.

Likewise, Plaintiffs' allegations regarding trade shows, steak dinners, "girls nights out," and other purported meetings do not imply a digoxin conspiracy. *See* CAC ¶¶ 155-57. Plaintiffs do not attempt to specifically plead that each Defendant attended these functions or that they related to digoxin. Indeed, most, if not all, of these allegations are appropriated wholesale from the AG Complaint, which has nothing to do with digoxin. Once again, therefore, Plaintiffs' allegations suggest, at most, an opportunity to conspire, but they cannot "sustain an inference that a conspiracy has taken place." *Petruzzi's IGA Supermarkets, Inc. v. Darling, Del. Co., Inc.*, 998 F.2d 1224, 1242 n.15 (3d Cir. 1993).

(c) Defendants' public statements do not aid Plaintiffs' cause.

Plaintiffs also cannot manufacture a digoxin conspiracy from public statements made by individual Defendants in investor communications and reports. Plaintiffs primarily rely on certain comments made by Lannett's CEO, Arthur Bedrosian, in the course of earnings calls, discussing the competitive landscape faced by Lannett. *See* CAC ¶¶ 123-33. The remarks indicated that

Lannett intended to compete vigorously for greater market share. *Id.* These comments certainly are no less (if anything, are more) consistent with unilateral conduct than they are with conspiracy. Executives, especially public company executives, must provide shareholders and investors with market forecasts and other predictions regarding price movements in the marketplace. Basing antitrust liability on such comments would chill pro-competitive, lawful conduct.

Indeed, there is nothing significant, from an antitrust perspective, about Bedrosian's comments, such as his alleged references to competitors or potential entrants acting "rational" with respect to pricing. *See, e.g.*, *id.* ¶ 130. Courts, including the Third Circuit, have recognized that in a concentrated industry, a firm's decision to follow a competitor's price increase is perfectly rational and unremarkable behavior. *See, e.g.*, *In re Chocolate Confectionary*, 801 F.3d at 401; *Valspar*, 152 F. Supp. 3d at 248-49. Bedrosian's acknowledgement of this market characteristic hardly implies collusion.

Nor can Bedrosian's comments reasonably be taken as improper price signaling as Plaintiffs appear to suggest. *See* CAC ¶ 126. Plaintiffs do not allege that Bedrosian referred to specific digoxin prices or the timing of any potential price increases during the relevant earnings calls. Courts in the Third Circuit have found far more detailed allegations and evidence of price signaling to be insufficiently suggestive of a conspiracy.

For example, in *Valspar*, the court rejected plaintiff's argument that even *specific* price announcements issued by the defendants were "price beacons to competitors for the purpose of gauging their willingness to raise prices." 152 F. Supp. 3d at 247-48. Despite evidence that such announcements were *intended* to prod competitors into following price increases, the court disagreed that an inference of conspiracy could be drawn. The court noted the "distinction between tacit and express collusion" and that there were obvious "lawful, non-collusive reasons for making

public price announcements." *Id*. at 248. Similarly here, Plaintiffs' reliance on Bedrosian's statements consists of "first assuming a conspiracy and then setting out to prove it." *Id*. at 249 (quoting *Blomkest Fertilizer, Inc. v. Potash Corp. of Saskatchewan*, 202 F.3d 1028, 1037 (8th Cir. 2000)). His comments cannot plausibly demonstrate an invitation to enter into a price-fixing agreement or that any such invitation was accepted. *See, e.g.*, *also Hall v. United Air Lines, Inc*., 296 F. Supp. 2d 652, 671 n. 23 (E.D.N.C. 2003) ("The public announcement of a pricing decision cannot be twisted into an invitation or signal to conspire; it is instead an economic reality to which all other competitors must react"); 6 Areeda & Hovenkamp, Antitrust Law, § 1435c at 281 (3d ed. 2010) (recognizing procompetitive justifications for public speech and announcements regarding pricing).

Moreover, some of Bedrosian's comments contradict the existence of the alleged digoxin conspiracy. For example, Plaintiffs allege that during a February 2015 earnings call, Bedrosian discussed uncertainty regarding a digoxin price increase, saying that Lannett was "also looking to capture *more* market share on the Digoxin [product]," and that Lannett would not "just let [its] competition take away [its] market share." CAC ¶ 132 (emphasis added). This does not plausibly suggest collusion but, on the contrary, price-based competition. Such competition would be unnecessary if there was an actual agreement to fix digoxin prices. *See also id*. ¶ 128 ("'But we're in the commodity business, so it's always hard to determine [the] point when you're going to get additional competition or when prices will erode as they generally do.'").

Statements made by other Defendants are equally insufficient to support a claim of conspiracy. Plaintiffs reference comments made by Impax's then-President of its generic division, Carole Ben-Maimon, acknowledging that Impax had followed a digoxin price increase instituted by Lannett in late 2013 and that the company believed its unilateral pricing decisions were rational

and profitable.[17] *Id.* ¶ 134. As discussed above, these types of comments do not suggest a conspiracy as a matter of law. And the alleged statements made by other Defendants (1) had nothing to do with digoxin, *see, e.g., id.* ¶ 138, (2) merely reported sales results and profits, *see e.g., id.* ¶¶ 141-42, and/or (3) innocuously discussed market conditions in the broader generic drug industry. *See, e.g., id.* ¶¶ 144-46. Once again, these allegations do not support the conspiracy Plaintiffs allege. As with most of Plaintiffs' allegations, were courts to infer a conspiracy from these statements, they would have to do so in nearly every Section 1 case.

Although this Court is not required to view each piece of "evidence" in isolation, Plaintiffs' conclusory, unexceptional allegations regarding Defendants' conduct never add up to anything like a plausible theory of conspiracy. In short, the CAC's meager allegations regarding a purported digoxin conspiracy do not plead the requisite "setting suggesting the agreement necessary to make out a § 1 claim." *Twombly*, 550 U.S. at 557.

III. Plaintiffs Fail To State A Plausible Claim That Defendants Conspired To Fix Prices Or Allocate Markets For Doxycycline

The same reasons that foil Plaintiffs' attempt to plead a plausible antitrust conspiracy for digoxin are also on full display with respect to doxycycline, and warrant the same result. As with digoxin, Plaintiffs' doxycycline claims lack direct evidence of an agreement and are equally bereft of allegations sufficient to provide circumstantial evidence of an agreement. The failure to plead either requirement warrants dismissal of the CAC.

A. Plaintiffs Do Not Allege Any Direct Evidence of a Doxycycline Conspiracy

Plaintiffs' CAC falls far short of the showing needed to sustain a direct-evidence conspiracy. There is certainly no hint of a "recorded phone call" or a specific "document or

[17] Plaintiffs wrongly assert that one of Ben-Maimon's statements relates to Impax and digoxin, *see* CAC ¶ 135, when in fact the February 20, 2014 earnings call transcript makes no reference to either digoxin or Lannett.

conversation explicitly manifesting" an agreement to fix prices or allocate markets for doxycycline. *See Mayor and City Council of Baltimore*, 709 F.3d at 129; *In re Ins. Brokerage*, 618 F.3d at 324 n.23. Indeed, the CAC lacks any allegations regarding when Defendants supposedly met or communicated to form the alleged doxycycline conspiracy, or which of Defendants' employees were involved. *Cf. Twombly*, 550 U.S. at 565 n.10; *Howard Hess Dental Labs,* 602 F.3d at 255.

In short, Plaintiffs do not allege any direct evidence of conspiracy. And so, unable to cite direct evidence of their own, Plaintiffs attempt to rely on the pleadings of others to make their case.

First, Plaintiffs cite to the AG Complaint referenced above. *See* CAC ¶¶ 195-99. Such pleading tactics do not pass muster. As the Supreme Court and the Third Circuit have both made clear, Rule 11 of the Federal Rules of Civil Procedure "imposes a non-delegable duty upon the signing attorney to conduct his own independent analysis of the facts and law which form the basis of a pleading or motion." *See Garr v. U.S. Healthcare*, 22 F.3d 1274, 1277-78 (3d Cir. 1994) (quoting *Pavelic & LeFlore Marvel Enter't Group*, 493 U.S. 120, 125-27 (1989)). Plaintiffs cannot shirk that duty by relying on someone else to do their work for them.

Regardless, the allegations in the AG Complaint do not contain any direct evidence of a doxycycline conspiracy, as that complaint relies on conclusory statements that do no more than recite the elements of a Section 1 claim. *See* AG Complaint ¶ 75 ("Heritage and Mylan executives agreed to allocate market share and refrain from competing with one another for customers in market for Doxy DR."). Plaintiffs also ignore a critical distinction between the AG Complaint and this case: the AG Complaint does not allege a conspiracy with respect to doxycycline generally, but only with respect to Doxy DR. Plaintiffs here do not plead that Actavis, Par, West-Ward, or

Sun ever manufactured or sold Doxy DR, CAC ¶ 98, and none of these four companies is a defendant in the AG Complaint. Moreover, an amended complaint was recently filed in that action, but it did not name any new defendants or new drugs. *See State of Conn. v. Aurobindo Pharma USA, Inc.*, No. 3:16-cv-02056-VLB (D. Conn.), Dkt. No. 168. Thus, Plaintiffs' attempt to piggy-back on the AG Complaint is both improper and ineffective

Second, Plaintiffs rely on guilty pleas by former Heritage executives Glazer and Malek, but such reliance is misplaced, as these guilty pleas do not absolve Plaintiffs of their obligation to plead allegations sufficient to satisfy *Twombly*.

At the outset, it should be re-emphasized that Heritage sold only Doxy DR. Glazer's and Malek's guilty pleas are therefore irrelevant to the claims against Actavis, Par, West-Ward, and Sun, companies not alleged to have produced Doxy DR. *See* CAC ¶ 98. Reliance on guilty pleas concerning other, supposedly "related products" is an insufficient substitute for factual allegations giving rise to a plausible inference of conspiracy. *See In re TFT-LCD (Flat Panel) Antitrust Litig.*, MDL No. 1827, 2010 WL 2609434 at *5 (N.D. Cal. June 28, 2010) (dismissing complaint relying on guilty pleas where there were insufficient "specific factual allegations to support the conspiracy claims in addition to allegations concerning guilty pleas with respect to the other products or markets."); *see also In re Hawaiian & Guamanian Cabotage Antitrust Litig.,* 647 F. Supp. 2d 1250, 1258 (W.D. Wa. 2009) (dismissing claim where plaintiff relied on DOJ investigation and guilty pleas relating to separate route in shipping industry involving some of defendants and noting "[s]imilar attempts at cross-fertilization have been rejected by other courts").

Moreover, even with respect to Doxy DR, Plaintiffs' reliance on the Glazer and Malek pleas fails. Neither the transcripts from the guilty plea hearings, nor any other publicly available documents from the criminal proceedings, provide any specifics as to the companies or individuals

with whom Glazer and Malek allegedly conspired, or when the alleged conspiracies were formed.[18] Thus the criminal proceedings fail to provide the "specific time, place, or person [other than Glazer and Malek themselves] involved in the alleged conspiracies" that are required to establish an antitrust conspiracy by direct evidence. *Twombly*, 550 U.S. at 565 n.10. Plaintiffs' allegations to the contrary are nothing more than the exact type of speculative, unfounded claims that do not survive scrutiny on a motion to dismiss.

B. Plaintiffs Fail to Sufficiently Allege a Conspiracy Claim Based on Circumstantial Evidence

Unable to allege any direct evidence of a conspiracy, and as noted above, Plaintiffs must set forth allegations showing that Defendants acted in parallel and allege sufficient circumstantial evidence—"plus factors"—suggesting that the parallel conduct was the result of an unlawful agreement rather than lawful independent behavior. *Twombly*, 550 U.S. at 556-57. As with digoxin, Plaintiffs fall far short here as well.

Even if Plaintiffs' allegations were sufficient to establish parallel conduct (which they are not), Plaintiffs' purported plus factors would support, at most, an inference that Defendants acted in accordance with conscious parallelism or market interdependence. That is not enough, even at the motion-to-dismiss stage, for their claims to move forward. *See Twombly*, 550 U.S. at 556 n.4 (requiring allegations of parallel conduct that "would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties"); *In re Chocolate Confectionary*, 801 F.3d at 398

[18] *See United States v. Glazer*, No. 2:16-cr-506, Doc. 1 (E.D. Pa.) (Information, filed Dec. 12, 2016); Doc. 15 (minute entry for plea, filed Jan. 9, 2017); *United States v. Malek*, No. 2:16-cr-508, Doc. 1 (E.D. Pa.) (Information, filed Dec. 13, 2016); Doc. 14 (minute entry for plea, filed Jan. 10, 2017).

("evidence of conscious parallelism cannot alone create a reasonable inference of a conspiracy"); *In re Ins. Brokerage*, 618 F.3d at 321 (same).

1. An average price increase does not establish that Defendants increased prices in parallel

Plaintiffs' circumstantial evidence-based claims fail at the outset, since there are no allegations that Defendants each charged the same price for any doxycycline product or that they instituted price increases in parallel. Absent such allegations, a price-fixing case premised on circumstantial evidence must be dismissed. *See Resco Prods.*, 158 F. Supp. 3d at 424 (assertions of general price movements could not demonstrate parallel increases absent evidence "of the amount or timing of any of the pricing increases it claim[ed] were the product of collusion.").[19]

Here, and just as with digoxin, Plaintiffs allege only a general market-wide "average" price increase for doxycycline that does not distinguish among or account for the various doxycycline types or dosages. *See, e.g.*, CAC ¶¶ 110-14. Other than a single allegation purporting to show doxycycline hyclate 100 mg prices for West-Ward, CAC ¶ 111, there are no allegations regarding the amount or timing of any price increase instituted by any Defendant. And even that single alleged fact says nothing about whether West-Ward's pricing changes preceded, followed, or were contemporaneous with those of any other Defendant. Additionally, there are absolutely no facts whatsoever about Doxy DR prices. There can be no parallel conduct when the CAC fails to allege facts as to who initiated the price increase, who followed the price increase, and when any of these purportedly unlawful acts occurred.

[19] *See also RxUSA Wholesale, Inc. v. Alcon Labs., Inc.*, 661 F. Supp. 2d 218, 233 (E.D.N.Y. 2009) (dismissing Sherman Act § 1 claim for failure to allege parallel conduct); *In re Travel Agent Comm'n Antitrust Litig.*, MDL No. 1561, 2007 WL 3171675, at *4 (N.D. Ohio Oct. 29, 2007) (dismissing claims because plaintiffs did not "put forth any 'factual matter' suggesting [four defendants] engaged in parallel conduct" (quoting *Twombly*, 550 U.S. at 556)), *aff'd*, 583 F.3d 896 (6th Cir. 2009).

Indeed, the CAC's few price-related allegations rely on the same flawed information sources Plaintiffs use for digoxin: (1) average market-wide prices for various doxycycline presentations, compiled from a survey of pharmacies and reported in the NADAC list, *see* CAC ¶¶ 113-16, and (2) average prices as reflected in a "U.S. Senate fact sheet." *See* CAC ¶ 110. Once again, however, Plaintiffs do not (and cannot) allege that the NADAC list or Senate fact sheet demonstrates the prices individual manufacturers charged or when any Defendant increased its price and, as previously noted, the Third Circuit has rejected the notion that "trend lines of average prices are a reliable indicator of transactional prices." *In re Baby Food*, 166 F.3d at 29.[20]

There are no facts pleaded in the CAC capable of demonstrating Defendants' parallel conduct, and the NADAC list average price cannot serve as a surrogate in the absence of these necessary allegations. As explained *supra* in Section II(A)(2)(a), an increase in the average prices of various doxycycline products says nothing about whether Defendants charged the same price or increased prices in parallel. Thus, Plaintiffs do not plead the "parallel" part of their "parallel plus" conspiracy claim, and the claim must therefore be dismissed without regard to the presence of any plus factors.

2. Plaintiffs do not adequately plead any plus factors

As with digoxin, Plaintiffs fail to adequately plead parallelism for doxycycline, but even if they had met this initial burden, the CAC still needs to be dismissed. Alleging parallelism without

[20] There are no reported court decisions relying on the NADAC list as a reliable source for actual drug prices. In *Wal-Mart Stores, Inc. v. Knickrehm*, 101 F. Supp. 2d 749 (E.D. Ark. 2000), the court analyzed studies prepared by Myers & Stauffer, the same accounting firm alleged to create the NADAC list. *See* CAC ¶ 40. The court found certain reliability problems, including issues in determining whether chain and non-chain pharmacies had different drug acquisition costs. *Knickrehm*, 101 F. Supp. 2d at 757-58. This suggests, again, that the NADAC list may hide important differences in the actual prices charged by individual manufacturers that make it irrelevant for purposes of evaluating the pricing conduct of individual Defendants.

a "plus factor" is insufficient to set out a claim under *Twombly*. *See supra* Section II(A)(2)(a). And Plaintiffs fail to allege plus factors with respect to doxycycline.

a. There are no allegations of motive or actions against self-interest.

The CAC does not explain Defendants' motive for entering the alleged conspiracy. To the extent Plaintiffs argue that Defendants were motivated by higher profits, *see* CAC ¶ 162, that does not imply collusion. *See In re Baby Food*, 166 F.3d at 134-35 (explaining that "[p]rofit is a legitimate motive in pricing decisions"); *Hyland,* 771 F.3d at 321 (same). Further, Plaintiffs' allegations regarding the doxycycline market's susceptibility to collusion, *see* CAC ¶ 202, cannot serve as a substitute for motive. *See In re Chocolate Confectionary*, 999 F. Supp. 2d at 789; *Schuykill Health*, 2014 U.S. Dist. LEXIS 103663 at *30. Nor is engaging in conscious parallelism a sign of an action against self-interest. *See supra* Section II(A)(2)(b)(1).

b. Plaintiffs do not allege any "traditional" evidence of a conspiracy.

The CAC also fails to plead the existence of any evidence implying a traditional conspiracy. As with digoxin, the CAC lacks actual allegations that could reasonably give rise to an inference that Defendants colluded with respect to doxycyline. *Cf. Superior Offshore Int'l*, 490 F. App'x at 499. Plaintiffs' allegations again consist of: (1) references to government investigations into the generic drug industry, including the guilty pleas of two former Heritage executives; (2) insinuations concerning Defendants' membership in a trade association and attendance at trade association meetings; and (3) a few public statements from certain Defendants' executives to investors. These allegations are neither capable of creating an inference of conspiracy nor sufficiently tailored to Plaintiffs' claims.

(1) Government investigations are not a plus factor here.

Plaintiffs' allegations regarding government investigations are insufficient to establish a plus factor. Investigations by Congress, the DOJ, and the Connecticut Attorney General into generic drug prices in general, and the guilty pleas of Glazer and Malek, are not sufficient to save Plaintiffs' claims. *See supra* Section II(A)(2)(b)(2)(a).

As previously discussed, courts assign little to no weight to such allegations. *See In re Graphics Processing Units*, 527 F. Supp. 2d at 1024 (holding existence of investigations "carries no weight" and is "non-factor" in "pleading an antitrust conspiracy claim"); *see also Footbridge Ltd. v. Countrywide Home Loans, Inc.*, No. 09-cv-4050-PKC, 2010 WL 3790810, at *5 (S.D.N.Y. Sept. 28, 2010) ("strik[ing] . . . allegations . . . based on pleadings, settlements, and government investigations"); *In re Hawaiian & Guamanian Cabotage*, 647 F. Supp. 2d at 1258 (dismissing claim where plaintiff relied on DOJ investigation and criminal charges and noting "[s]imilar attempts at cross-fertilization have been rejected by other courts, and the Court finds plaintiffs' invocation of the DOJ investigation equally unavailing"). Failure to ascribe any weight to such allegations makes sense because "the mere occurrence of [an] investigation is equally consistent with Defendants' innocence." *Superior Offshore Int'l*, 738 F. Supp. 2d at 517.

And although Glazer and Malek pleaded guilty to their roles in a conspiracy concerning Doxy DR—the only doxycycline product Heritage makes—there are no guilty pleas, or even indictments, evidencing a broader doxycycline conspiracy as alleged in Plaintiffs' CAC.[21]

[21] Indeed, the CAC fails to allege that Sun and Actavis are being investigated with respect to any doxycycline presentation. *See* CAC ¶¶ 189, 191.

(2) The trade association allegations are also insufficient.

The CAC either speculates about the import of Defendants' involvement in the GPhA, *see* CAC ¶ 148 ("DOJ *is investigating whether* trade organizations are a potential vehicle for collusion") (emphasis added), or regurgitates conclusory allegations from the AG Complaint that "the defendants [excluding Actavis, Par, West-Ward and Sun] routinely coordinated their schemes through . . . industry trade shows[.]" *Id.* ¶ 147. No deference is due to a conclusory allegation lifted from another complaint, and it is black-letter law that "possibility" is not "plausibility." *Burtch*, 662 F.3d at 221. Plaintiffs do not allege any facts demonstrating that Defendants' participation in the GPhA plausibly facilitated price-fixing for doxycycline. *Cf. Consol. Metal Prods., Inc. v. Am. Petroleum Inst.*, 846 F.2d 284, 293-94 (5th Cir. 1988) ("[A] trade association is not by its nature a 'walking conspiracy.'"). As with digoxin, the CAC contains no specific allegations that Defendants communicated about doxycycline through the GPhA; nor does it provide any factual allegations to the effect that the price of doxycycline (or any other drug for that matter) was actually related to GPhA activities. Indeed, the CAC does not allege that all Defendants attended GPhA events. For example, Plaintiffs make no allegations that Mayne representatives attended any event sponsored by the GPhA, or that West-Ward attended any events until well after the alleged doxycycline price increases. CAC ¶ 154.

Courts universally recognize that "mere membership in a trade association, including attendance at meetings, is insufficient without more to give rise to an inference of conspiracy." *Resco Prods.*, 158 F. Supp. 3d at 425 (quoting *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 513 F. Supp. 1100, 1149 (E.D. Pa. 1981)), and Plaintiffs' attempt to rely on insinuation and conclusory allegations to manufacture a "plus factor" fails for doxycycline.

(3) Defendants' public statements do not aid Plaintiffs' cause.

In yet another attempt to manufacture the impression of a conspiracy, Plaintiffs rely on a grab bag of statements from investor communications by various defendants, such as West-Ward's statement about "the exceptional profitability of doxycycline," *id.* ¶ 137, Sun's reference to doxycyline as a "low competition product," *id.* ¶ 143, Actavis's referring to a "favorable" pricing environment, *id.* ¶ 145, and Par's referring to "consolidation and maturation of competitors [having] stabilized the pricing environment."[22] *Id.* ¶ 146.

These statements do not constitute a plus factor for doxycycline for the same reasons they do not constitute a plus factor for digoxin. *See supra* Section II(A)(2)(b)(2)(c). The Third Circuit has consistently held that "communications between competitors do not permit an inference of an agreement to fix prices unless those communications rise to the level of an agreement, tacit or otherwise." *In re Baby Food*, 166 F. 3d at 126. Far from "not rising to the level of agreement," these communications *are not even between competitors*, nor do any of the statements in any way indicate that there have been any actual communications between Defendants with respect to pricing and marketing doxycycline, much less an express price-fixing agreement. None of these statements remotely demonstrates any agreement to fix prices in any way, shape, or form. Contradicting themselves, Plaintiffs attempt to use statements made by Defendants' executives to investors and journalists, in public and hidden from no one, as somehow establishing a clandestine price-fixing and market-allocating conspiracy.

As with all of the Plaintiffs' allegations, these claims are long on verbiage, but short on actual facts, and the CAC should be dismissed.

[22] Statements made by Lanett's CEO during earnings calls have no relation to the alleged doxycycline conspiracy as Lannett is not alleged to, and does not, manufacture any doxycycline product at issue here.

* * * * *

The collective weight of these deficiencies in Plaintiffs' CAC compels the conclusion that this case should be dismissed, and sets this case apart from others that have survived at the motion-to-dismiss stage, such as *In re Blood Reagents Antitrust Litig.*, 756 F. Supp. 2d 623 (E.D. Pa. 2010).

In stark contrast to the CAC here, the *Blood Reagents* plaintiffs pleaded numerous detailed factual allegations against each defendant that the court found established a context of concerted action when viewed together. *See id.* at 631. The price increase at the beginning of the alleged conspiracy period marked the first industry price increase in *15* years, and each defendant's prices kept increasing, often by triple digits, for the next *eight* years (in contrast to the limited period of average price increases alleged here, followed by decreases).[23] *Id.* Further, the defendants cancelled contracts with group purchasing organizations that would not accept price increases, and one defendant publicly stated it did so solely "for the purpose of increasing prices to the members of each group." *Id.* at 627. The defendants also hired each other's high-level employees and "the personal networks and relationships that these employees brought with them [made] the allegations of conspiracy more plausible." *Id.* at 632.

Unlike the specific allegations of the *Blood Reagents* plaintiffs, Plaintiffs in this case come nowhere close to meeting the requirement of plausibility. *See also In re McWane, Inc.*, No. 9351, 2013 FTC LEXIS 76, at *658 n.18 (F.T.C. May 8, 2013) (noting argument that "mere membership

[23] Dr. Schondelmeyer's Congressional report, on which Plaintiffs place great emphasis, explains, "While there are a number of generic drug products with very large price increases, *this is not a new phenomenon*." Ex. A, Schondelmeyer Rpt. at p. 16 (emphasis added). The report references an earlier study which found that "of 35,143 drug products . . . 13.5% of them had experienced one or more extraordinary price increases in the period 1988 to 2008. While a few of these extraordinary price increases occurred in the 1990s, the vast majority were found in the 2000s." *Id.* Accordingly, the price increases alleged in the CAC do not represent an abrupt, unprecedented shift in industry pricing practices.

in a trade association [was] a 'plus factor' evincing agreement [was] without merit" and commenting that counsel's reliance on *Blood Reagents* was misplaced), *aff'd in relevant part*, 2014 FTC LEXIS 28 (F.T.C. Jan. 30, 2014).

CONCLUSION

Try as they might, Plaintiffs do not, and cannot, plead a plausible antitrust claim against Defendants here. A two-product, over-arching conspiracy is illogical because Defendants that only make one drug would have absolutely no reason to be in a conspiracy to fix the price of a product or allocate markets for a product they do not make. Plaintiffs' allegations related to the purported doxycycline and digoxin conspiracy also do not hold up to scrutiny, as they are overrun by conclusory statements devoid of any actionable facts. For all of the foregoing reasons, Defendants respectfully request that the Court dismiss the CAC with prejudice.

Respectfully submitted,

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Dated: March 28, 2017

EXHIBIT "A"

Statement on

Why Are Some Generic Drugs Skyrocketing in Price?

Statement before

Senate Committee on Health, Education, Labor and Pensions (HELP)
Congress of the United States
November 20, 2014

Statement of

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Statement on
Why Are Some Generic Drugs Skyrocketing in Price?

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Thank you Senator Sanders and members of the Senate Committee on Health, Education, Labor and Pensions (HELP) for this opportunity to provide information and insights on drug price trends related to generics and other pharmaceutical products. I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Management & Economics at the University of Minnesota where I serve as Director of the *PRIME* Institute. The *PRIME* Institute focuses its research on policy issues related to pharmaceutical economics and the management of drug expenditures at all levels in society. These remarks are my own views based upon my research and experience in studying the pharmaceutical marketplace for over forty years. Previously, I have had the opportunity to serve Congress as a member of the Prescription Drug Payment Review Commission (established under the Catastrophic Coverage Act of 1988), as an author or co-author of several legislatively mandated Reports to Congress, and through testimony before Congressional committees on numerous occasions.

This hearing is being held to examine "Why are some generic drugs skyrocketing in price?" Various aspects of this issue are addressed in my written remarks which include comments on: (1) improved coverage and access to pharmaceuticals; (2) the role of generics in the U.S. pharmaceutical market; (3) recent price trends for brand and generic prescription drug products; (4) signals of market failure in the pharmaceutical market; and (5) policy options to address skyrocketing drug prices. I will briefly address each of these topics and describe their relationship to the skyrocketing generic drug prices being observed in the market.

Improved Coverage and Access to Pharmaceuticals

Actions taken by Congress over the past decade have expanded health insurance coverage, in general, and more specifically prescription drug coverage. Two major pieces of legislation have been enacted and implemented in the past decade: (1) The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA); and (2) The Patient Protection and Affordable Care Act (PPACA)--commonly called the Affordable Care Act (ACA) (2010).

First, the MMA established the Medicare Prescription Drug Program, also known as Medicare Part D. The MMA's most prominent feature was the introduction of an entitlement benefit for Medicare beneficiaries covering prescription drugs through tax breaks, subsidies, premiums, and other forms of cost-sharing. The Medicare Part D program was implemented on January 1, 2006. The ACA was the second major piece of legislation passed by Congress in less than ten years. The ACA was enacted with the goals of increasing the quality and affordability of health insurance, lowering the uninsured rate by expanding public and private insurance coverage, and

reducing the costs of healthcare for individuals and the government. While some of the provisions of the ACA were implemented as early as 2010, the major provisions went into effect on January 1, 2014. Both the MMA and the ACA have expanded the number of persons with health insurance including prescription drug coverage. Gallup has estimated that the uninsured rate for adults (persons 18 years of age and over) was 13.4% as of the second quarter of 2014, down from 18.0% in the third quarter of 2013 when the health insurance exchanges created under the Patient Protection and Affordable Care Act (PPACA or "Obamacare") first opened.[1]

As a result of the MMA and the ACA, more Americans have public or private health insurance which includes coverage of prescription drugs. This expansion of health insurance and drug benefit coverage has been accomplished using a combination of premiums, subsidies, taxes and penalties for lack of coverage. The percent of Americans with prescription drug coverage is at an all-time high (about 86% of the U.S. population).

Drug therapy is perhaps the most widely used form of therapy in health care. Each year in the U.S. there are more than 4 billion outpatient prescriptions provided to 310 million Americans.[2] This means that each American gets 12 or more prescriptions per person per year on average. In addition to outpatient prescriptions in retail settings, patients use drug therapy in virtually all other areas of health care such as hospitals, nursing homes, physicians' offices and clinics, dentists' offices, government facilities, public health clinics, and other settings. Each year there are 20 to 40 new molecular entities that are approved by the Food & Drug Administration for marketing in U.S.[3] These new drug (or biological) approvals are usually for innovative drug therapies that almost always have one or more patents and/or other forms of exclusivity. Often these new drug therapies hold the promise of treating a previously untreated disease or providing safer or more effective therapy to replace older drugs on the market. Also, keep in mind that today's new and innovative drug therapies and biologicals are the drug products that will become available as generics or biosimilars in the future.

Role of Generics in the U.S. Pharmaceutical Market

In 1984, Congress enacted the Hatch-Waxman Act also known as the "Patent Term Restoration and Drug Price Competition Act." The Hatch-Waxman Act ("the Act" or "Hatch-Waxman") simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need for generic companies to file lengthy and costly New Drug Applications (NDAs) in order to obtain FDA approval.[4] The Act also eliminated the duplicative clinical trials in patients that had been required for a generic drug to obtain approval from the FDA. Instead, drug companies are permitted to file Abbreviated New Drug Applications (ANDAs) and to rely on the safety and

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[1] Levy,Jenna, Well-Being, Gallup Release Date: October 8, 2014, found on website at: http://www.gallup.com/poll/178100/uninsured-rate-holds.aspx.
[2] IMS Institute for Healthcare Informatics. Medicine use and shifting costs of healthcare. April 2014., p. 49.
[3] U.S. Food & Drug Administration. Novel New Drugs, 2013 Summary. January 2014, p. 3.
[4] *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market*, Congressional Budget Office, July 1998, ("CBO Report"), at xii.

efficacy data already supplied to the FDA by the original NDA holder for a given drug. Hatch-Waxman also added a number of provisions to the statutory scheme, which extended the time during which brand name (and patented) drugs may enjoy patent and other forms of market exclusivity.

The main purpose of the Hatch-Waxman Act was to balance two competing aims: (1) the protection of intellectual property rights of those who discover and market new and novel drug therapies, by "Patent Term Restoration," in order to account for and to restore part of the time a drug product was under review by the FDA; and (2) the benefit to the American public that can be provided by "Drug Price Competition" resulting from prompt market entry of less expensive generic drug products that are therapeutically equivalent to the brand name drug product.

Generic drugs are essentially exact substitutes for brand name drugs which have met the same exact standards for bioequivalence and pharmaceutical equivalence set by the FDA. Generic drug products are approved by the FDA through an ANDA and contain the same active ingredient(s), in the same dosage form, in the same strength, and are bioequivalent to the reference listed drug (RLD) (i.e., the original brand name version of the drug approved by FDA through a New Drug Application (NDA)).[5] The FDA through its review process assures the same clinical effect and safety profile for brand and generic drug products rated as therapeutically equivalent.[6] According to the FDA, "Products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product."[7]

Evaluations of therapeutic equivalence for prescription drugs are based on scientific and medical evaluations by the FDA. Products evaluated as therapeutically equivalent can be expected, in the judgment of the FDA, to have equivalent clinical effect and no difference in their potential for adverse effects when used under the conditions of their labeling.[8] If the brand and generic products are shown to be therapeutically equivalent, and therefore interchangeable, they are rated as "A" by the FDA. Because there is no difference in efficacy and safety between the FDA-approved brand and generic versions of a drug product, they are freely substitutable and interchangeable from a clinical standpoint.

Brand-name drugs that are approved for sale by the FDA are sometimes protected by one or more patents or other forms of exclusivity[9], which provide the patent owner (or exclusivity holder) with the ability to ask a court to enforce an exclusive right to sell that drug in the United

[5] While a generic drug must have the same active ingredient in the same amount as the brand drug, the generic can use different inactive ingredients.
[6] Orange Book, 27th ed. (12/31/2006) *Preface,* p. vi.
[7] Orange Book, 27th ed. (12/31/2006) *Preface,* p. x.
[8] Orange Book, 27th ed. (12/31/2006) *Preface,* p. x.
[9] Drug companies may receive FDA-granted exclusivity periods for several reasons including: (1) orphan designation; (2) completing FDA-requested pediatric studies; (3) conducting new clinical trials that result in substantial label changes; and (4) other reasons.

States for the duration of the patent, or patents, plus any other extension times afforded by law. The Hatch Waxman Act requires the brand company to file with the FDA the patent number and expiration date of any patent covering the drug in question.

Patent information received by the FDA with respect to approved drugs is published in the FDA's "Orange Book," where such information can be found and consulted by future FDA applicants. In accepting and publishing patent information in the Orange Book, the FDA's role is purely ministerial. The FDA does not verify the facts supplied to it by the patent holder, but instead relies on the good faith and presumed truthfulness of the original NDA holder. An invalid patent that is issued will be listed in the FDA Orange Book and may delay generic competition.

The first generic competitor to enter a market typically does so at a price substantially lower than the price of the equivalent brand name drug, and quickly takes a substantial amount of the share of the market for the particular drug "molecule" away from the brand name drug manufacturer. As additional generic competitors come to market, the prices of the generic drug competitors continue to fall compared to the brand price, and their combined share of the market for the molecule, relative to the brand name equivalent, usually continues to grow.

The price competition engendered by generic drug manufacturers affects all purchasers of the drug, who are able to buy the generically equivalent chemical substance (the molecule) at much lower prices. Pharmacies and pharmacists – the people and organizations who dispense drugs to patients – can and do substitute A-rated generic drugs for brand name drugs wherever possible in order to lower their own costs and those of their customers. The incentive for pharmacists and patients to engage in routine and easy substitution of A-rated generics has been enhanced over the years by managed care organizations, who, to encourage the use of cost-saving generic drugs, typically place A-rated generic drugs on the "first tier" of their formularies, which corresponds to a lower co-pay level.

Pharmacy-driven substitution is extremely rapid and robust in causing the share of the market for the particular drug molecule to shift away from the more expensive brand name drug product and toward the less-expensive A-rated generic equivalents. When easy and routine pharmacy substitution is possible, i.e., when there is an A-rating, all purchasers of the brand name drug – pharmacies of all types (including independent, chain, food and drug stores, and mail order pharmacies), wholesalers and distributors, managed care organizations, hospitals, group purchasing organizations (GPOs) and other "classes of trade" – rapidly begin to purchase the generic version in lieu of the brand version. In addition to my own research, there are a large number (indeed hundreds) of sources -— both published and unpublished — describing the effects of generic competition in pharmaceutical markets. These sources include published articles and research papers, unpublished analyses and research papers, policy papers, government studies and documents, dissertations, databases, and other sources describing the

effects of generic competition.[10] In the course of my work, I have reviewed most of this research, as it is available in the public domain. I have also conducted studies on the generic pricing and generic penetration rates of nearly all new molecular entities (drug molecules) that have faced generic competition since 1983.

Testimony by the FDA's Director of the Office of Generic Drugs before the Senate Special Committee on Aging in July 2006 reported that "[t]he Hatch-Waxman Amendments have been very successful and have provided for the approval of over 8,000 generic drug products. These products are lower cost, high quality products that have saved the American public and the

[10] Among the principal studies in the scientific and economic literature which analyze the effects of generic competition are the following:

a. *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market*, Congressional Budget Office, July 1998 (Ex. 96);
b. Jae P. Bae, *Drug Patent Expirations and the Speed of Generic Entry*, Health Services Research, Vol. 32, No. 1, pp. 87-101, April 1997 (Ex. 98);;
c. Richard G. Frank and David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, Journal of Economics and Management Strategy, Vol. 6, Spring 1997, pp. 75-90 (Ex .99);
d. Henry Grabowski and John Vernon, *Longer Patents for Increased Generic Competition in the U.S.: The Hatch-Waxman Act After One Decade*, PharmacoEconomics, 1996 (Ex. 100);
e. *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, Congressional Budget Office, 1996 (Ex. 101);
f. *Pharmaceutical R&D: Costs, Risks, and Rewards*, Office of Technology Assessment, February 1993 (Ex. 102);
g. Henry Grabowski and John Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, Journal of Law and Economics, October 1992, p. 339 (Ex. 103);
h. Richard E. Caves, Michael D. Whinston, and Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry, Brookings Papers on Economic Activity:* Microeconomics, 1991, pp. 1-66 (Ex. 104);
i. Alison Masson and Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws*, Federal Trade Commission, 1985 (Ex. 105);
j. Jerry I. Treppel, Andrew S. Forman, Daniel A. Seto, Geoffrey G. O-Brien, *Specialty Pharmaceuticals Industry: The Thrifty Fifty* (New York: Warburg Dillon Read, May 5, 1999) (Ex. 106);
k. Kirking D.M., Ascione F.J., Gaither C.A., Welage L.S., *Economics and Structure of the Generic Pharmaceutical Industry*, Journal of the American Pharmaceutical Association, 41: 578-584, 2001(Ex. 107);
l. Ascione F.J., Kirking, D.M., Gaither C.A., Welage L.S., *Historical Overview of Generic Medication Policy*, Journal of the American Pharmaceutical Association, 41: 567-577, 2001(Ex. 108);
m. Suh, D.C., Manning W.G., Schondelmeyer, S., Hadsall, R., *Effect of Multiple-Source Entry on Price Competition after Patent Expiration in the Pharmaceutical Industry*, Health Services Research, 35: 529-547, 1993 (Ex. 109);
n. Reiffen, D. and Ward, M.R. (2002*), Generic Drug Industry Dynamics* FTC Working Paper 248 http://www.ftc.gov/be/workpapers /industrydynamicsreiffenwp.pdf (Ex. 110);
o. Rozek, P.R., Berkowitz, R, *The Cost to the U.S. Health Care System of Extending Marketing Exclusivity for Taxol*, Journal of Research in Pharmaceutical Economics, 9(4): 21-41, 1999 (Ex. 111);
p. Hong, S.H., Shepherd, M.D. and Wan, T.T., *The Impact of Product Line Extensions on Rising Prescription Drug Prices.* Manuscript in progress (2003) abstract presented at the 130th Annual Meeting of the American Public Health Association; Philadelphia, PA (November 9-13, 2002) (Ex. 112);
q. Andrew S. Forman and David S. Moskowitz, *Specialty Pharmaceuticals: Rising to Another Level* (New York: Warburg Dillon Read, May 5, 2000) (Ex. 113).

government billions of dollars."[11] The Congressional Budget Office has credited the Hatch-Waxman Act and, importantly, the process for easy and routine A-rated generic substitution by pharmacists with providing meaningful economic competition from generic drugs, and with achieving billions of dollars of savings for drug purchasers such as consumers and employers.[12] The rate of generic dispensing has reached an all-time high with generic drug products being dispensed for 77% to 85% of all outpatient prescriptions in 2012 and 2013.[13, 14]

In other words, generic drug products play a critical role in the U.S. market because they are the only form of direct economic and price competition from identical, therapeutically equivalent drug products which can be legally substituted for brand name prescription drugs. Generics can perform this critical function effectively, however, only through the A-rated substitution mechanism. Generic drugs are essentially exact substitutes for brand name drugs which have met standards for bioequivalence and pharmaceutical equivalence set by the FDA. Without the presence of, or ability of, purchasers to choose an A-rated therapeutically equivalent generic alternative, brand name products will face relatively little effective price or economic competition. The availability and use of FDA-approved A-rated generics provides the key mechanism for assuring that a competitive market for drug products exists, allowing patient-users to achieve equivalent efficacy and safety with increased access and decreased cost. This process of making generic drug products readily available and routinely substitutable at the pharmacy level is what brings effective economic competition to the generic segment of the prescription drug marketplace. Generic drug companies serve a vital role in the pharmaceutical marketplace, and as Hatch-Waxman intended, are meant to stimulate "Drug Price Competition."

Recent Price Trends for Prescription Drug Products

What are the recent price trends for prescription drug products in the past few years? Research performed by the *PRIME* Institute at the University of Minnesota, in conjunction with the AARP Public Policy Institute, has examined the price trends for various segments of the pharmaceutical market including brand name, generic, and specialty products. Actual transaction prices[15] at the

[11] Statement of Gary Buehler, R.Ph., Director of the Office of Generic Drugs, Center for Drug Evaluation and Research, FDA, before Special Committee on Aging, United States Senate (July 20, 2006), *available at* http://www.fda.gov/ola/2006/genericdrugs0720.html.

[12] Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market, July 1998, p. ix ("CBO Report").

[13] Pharmacy Times, November 12, 2013, "2012 Generic Drug Dispensing Surpasses 2011 for New Record," found on web site at: http://www.pharmacytimes.com/publications/issue/2013/November2013/2012-Generic-Drug-Dispensing-Surpasses-2011-for-New-Record.

[14] The Express Scripts Lab, The 2013 Drug Trend Report, April 2014, p.67.

[15] The retail prices used in this report are drawn from Truven Health's MarketScan® Commercial Database and MarketScan® Medicare Supplemental Database (Truven Health MarketScan® Research Databases). The prices reflect the actual total price for a specific prescription that a pharmacy benefit manager (PBM) bills to a specific health plan for consumers enrolled in employer-sponsored or government-sponsored (i.e., Medicare or Medicaid) health plans and not simply the out-of-pocket cost (such as the copay) which a consumer would pay at the pharmacy. These amounts may or may not reflect what the PBM paid the pharmacy or the usual and customary price that a pharmacy would charge a cash pay consumer for the same prescription.

retail level for prescription drugs widely used by older Americans have been examined over the time period December 31, 2005 to December 31, 2013.[16] (See the AARP Public Policy Institute Report for details on the study methods.) We have completed the brand name drug price trend analysis and we are continuing to examine the generic and specialty drug price trend analysis. I will report here a summary of the brand name drug price trends for 2013 and preliminary findings from the generic drug price trends for 2013.

Brand Name Drug Price Trends for 2013. The trends reported here are annual price changes based on the 12-month rolling average for the period from December 31, 2012 to December 31, 2013. So let's examine price changes in the market for brand name drug products in 2013.

- Retail prices for the 227 brand name drug products[17] most widely used by older Americans rose 12.9 percent in 2013 (Figure 1).[18]
- The average annual retail price increase in 2013 for these brand name prescription drug products was more than eight times higher than the rate of general inflation (12.9 percent vs. 1.5 percent).[19]
- The average annual retail price increase for brand name prescription drug products in 2013 (12.9 percent) was more than two times higher than the average annual brand name drug price increase in 2006 (5.7 percent).
- The average annual cost for one brand name medication used on a chronic basis was nearly $3,000 in 2013.
    - For a consumer who takes three brand name prescription drugs on a chronic basis, the annual cost of therapy would have been more than $8,800 during 2013—more than double the cost seen 8 years earlier.
- Between January 2006 and December 2013, retail prices for 140 chronic use brand name drugs that have been on the market since the beginning of the study increased cumulatively over 8 years by an average of 113.0 percent.
    - The cumulative general inflation rate in the U.S. economy was 18.4 percent during the same 8-year period.

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[16] Schondelmeyer, Stephen W. and Purvis, Leigh, Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2006 to 2013, AARP Public Policy Institute, Rx Price Watch Report #2014-03, November 2014. 38 pp.

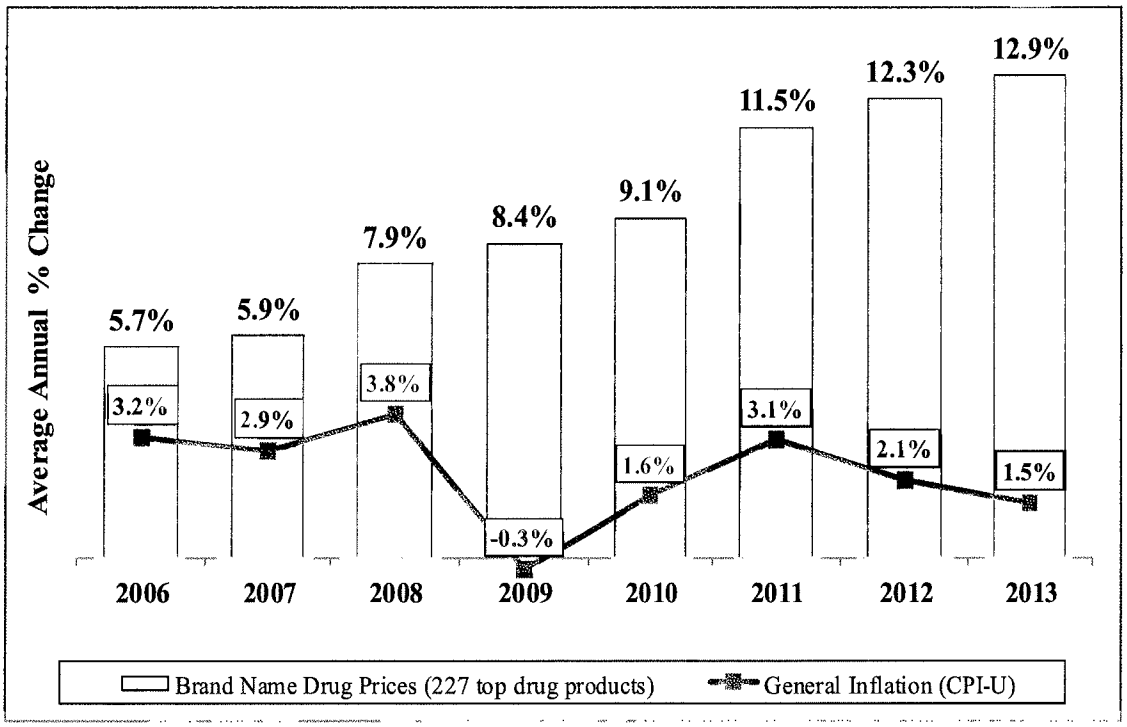
[17] The market basket for this analysis had 227 brand name prescription drug products. Some critics of the Rx Price Watch reports have suggested that brand name drug products in our market basket that subsequently face generic competition should be excluded from this analysis because they may be skewing the results upward. However, when only the 169 brand name drug products with no generic competition are considered, the average annual price change was 13.2 percent in 2013—higher than the 12.9 percent price trend shown in this report (for additional information and analysis, see Appendix B).

[18] When measured as a 12-month rolling average and weighted by actual 2011 retail prescription sales to older Americans ages 50 and above, including Medicare beneficiaries.

[19] The general inflation rate used in this report is based on the average annual rate of change in the Consumer Price Index-All Urban Consumers for All Items (seasonally adjusted) (CPI-U), Bureau of Labor Statistics series CUSR0000SA0.

- Retail prices increased in 2013 for 97 percent (219 of 227) of the widely used brand name prescription drug products in the study's market basket. All but two of these retail price increases (217 of 227) exceeded the rate of general economic inflation in 2013.
- Retail prices for all 32 of the drug manufacturers with at least two brand name drug products in the study's market basket increased faster than the rate of general inflation (1.5 percent) in 2013.
    - Twenty-two drug manufacturers, including the "All Other" category, had average annual price increases for their brand name drugs of 10 percent or more during 2013.
- All but two of the 46 therapeutic categories of brand name drug products had average annual retail price increases that exceeded the rate of general inflation in 2013, with price increases by therapeutic category ranging from 4.2 percent to 41.1 percent.

Figure 1. Average Annual Brand Name Drug Prices Continue to Grow Substantially More than General Inflation in 2013

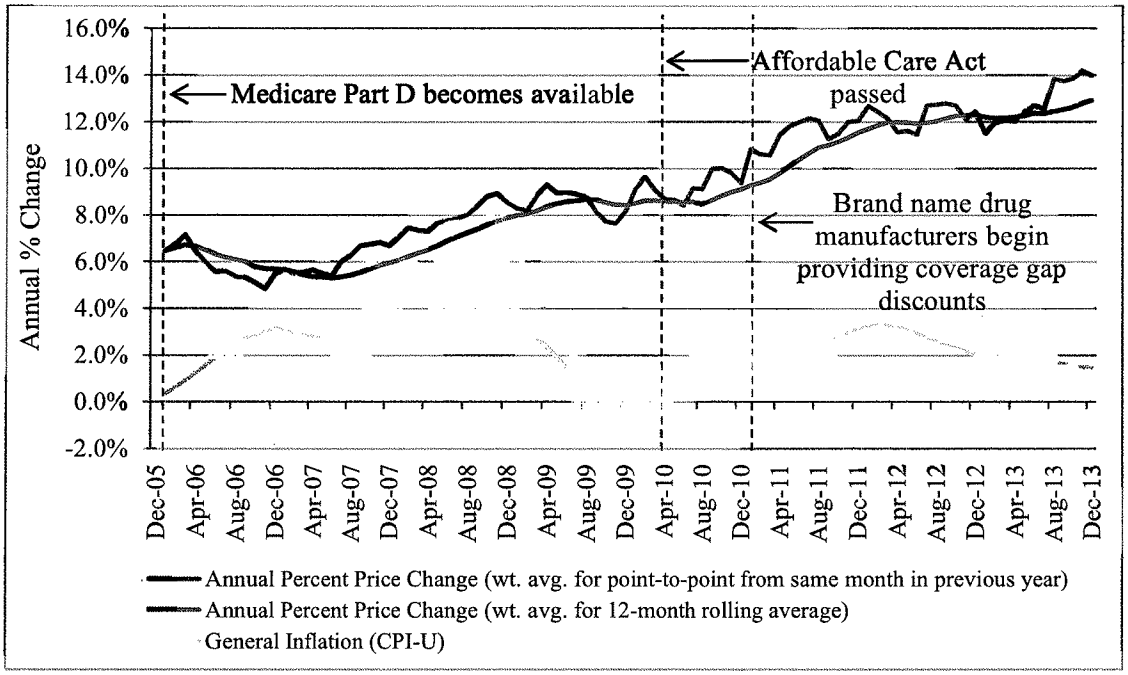


Note: Calculations of the average annual brand name drug price change include the 227 drug products most widely used by older Americans (see Appendix A).
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Figure 2 shows the percent change in brand name drug prices for each month compared with the same month in the previous year. This trend is shown alongside the 12-month rolling average to allow more detailed examination of the rate and timing of retail brand name drug price changes over the entire study period. This analysis reveals three broad trends since implementation of the Medicare Part D program:

- The retail price of brand name drug products has steadily increased over time since 2006;
- Brand name drug price increases at the retail level have been substantially higher than the rate of general inflation; and
- The gap between the rate of brand name drug price change and the rate of change in general inflation has substantially widened over the period from 2006 to 2013. This gap has ranged from less than a two-fold difference in 2006 to nearly a nine-fold difference in 2013.

Figure 2. Rolling Average and Point-to-Point Changes in Retail Prices for Most Widely Used Brand Name Prescription Drugs Were Well Above Inflation from 2006 to 2013



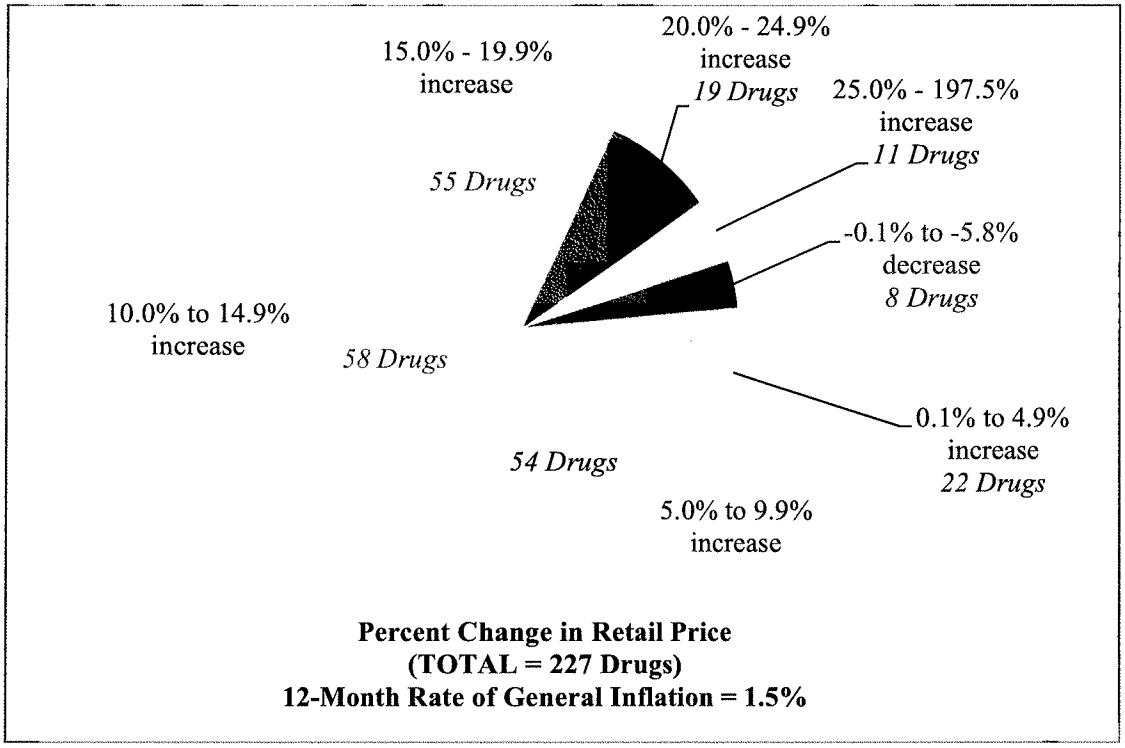
Note: Calculations of the average annual brand name drug price change include the 227 drug products most widely used by older Americans (see Appendix A).
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Retail prices for 97 percent (219 of 227) of the most widely used brand name prescription drug products had price increases in 2013 (Figure 6). Prices for 96 percent (217 of 227) of the most widely used brand name prescription drug products increased faster than the rate of general inflation (1.5 percent) in 2013.

Among the 87 percent (197 of 227) of brand name drug products with annual retail price increases of more than 5.0 percent—or more than three times the rate of inflation—in 2013:

- Nearly one-half (49.4 percent or 112 drug products) increased between 5.0 percent and 14.9 percent—that is, five to ten times the rate of general inflation in the economy; and
- More than one-third (37.6 percent or 85 drug products) had an annual increase of 15.0 percent or more which is ten or more times the rate of general inflation in the economy.

Figure 3. Retail Prices Increased by More than 10 Percent in 2013 for Almost Two-Thirds of the Most Widely Used Brand Name Drugs



Note: Calculations were made using brand name drug price change from December 31, 2012 to December 31, 2013, and the analysis included the 227 brand name drug products most widely used by older Americans (see Appendix A).
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Eight of the widely used brand name drug products in this study had unusually high 8-year cumulative price increases (i.e., the end of 2005 to the end of 2013). The brand name drug products with unusual price increases were:

- Uroxatal 10 mg tablets are a drug product used to treat prostatic hypertrophy. This brand name drug product had a price increase of 512.7 percent—more than a six-fold increase—over the 8-year study period ending in 2013.
- Solaraze Gel 3% is a transdermal topical drug product used to treat a severe skin condition. This brand name drug product had a price increase of 445.9 percent—more than a five-fold increase—over the 8-year study period ending in 2013.
- Humulin R U-500—used to treat diabetes—had an 8-year price increase of 361.0 percent over the entire 8-year study period ending in 2013. This retail price increase shows more than a four-fold jump in price over 8 years.
    - It is notable that the vast majority of this increase took place over the past 3 years (i.e., 2011 to 2013). Since insulins are biological products they currently do not have generic competition but they are likely to face entry from biosimilar products within the next few years.[20]
- Prandin 2 mg tablets—another drug for diabetes—had an 8-year price increase of 295.3 percent over the entire 8-year study period. This retail price increase is nearly a four-fold jump in price from 2006 to 2013.
- Atrovent HFA 17 mcg/actuation—a respiratory inhaler and bronchodilator—increased in retail price by 252.4 percent over the 8-year study period. This retail price increase is more than a three-fold jump in price over 8 years from 2006 to 2013.
- Benicar 40 mg tablets—used to treat hypertension—had a price increase of 207.1 percent over the 8-year study period ending in 2013. This retail price increase is more than a three-fold growth in price over 8 years.
- Lunesta 3 mg tablets (and Lunesta 2 mg tablets)—drug products used for sedation—had an 8-year retail price increase of 203.7 percent. This retail price increase represents a three-fold price jump in 8 years.

Generic Drug Price Trends for 2013. The trends reported here are annual price changes based on the 12-month rolling average for the period from December 31, 2012 to December 31, 2013. So let's examine preliminary findings from the generic drug price trend analysis for 2013. In the past several years (i.e., 2006 to 2012), the average generic price for widely used drugs decreased with the amount ranging from -7.2% to -14.5%. While the final data for 2013 has not yet been completed, the generic price effect for 2013 is also expected to be a decrease, but not as much of a decrease as seen in the previous years of the study (i.e., 2006 to 2012).

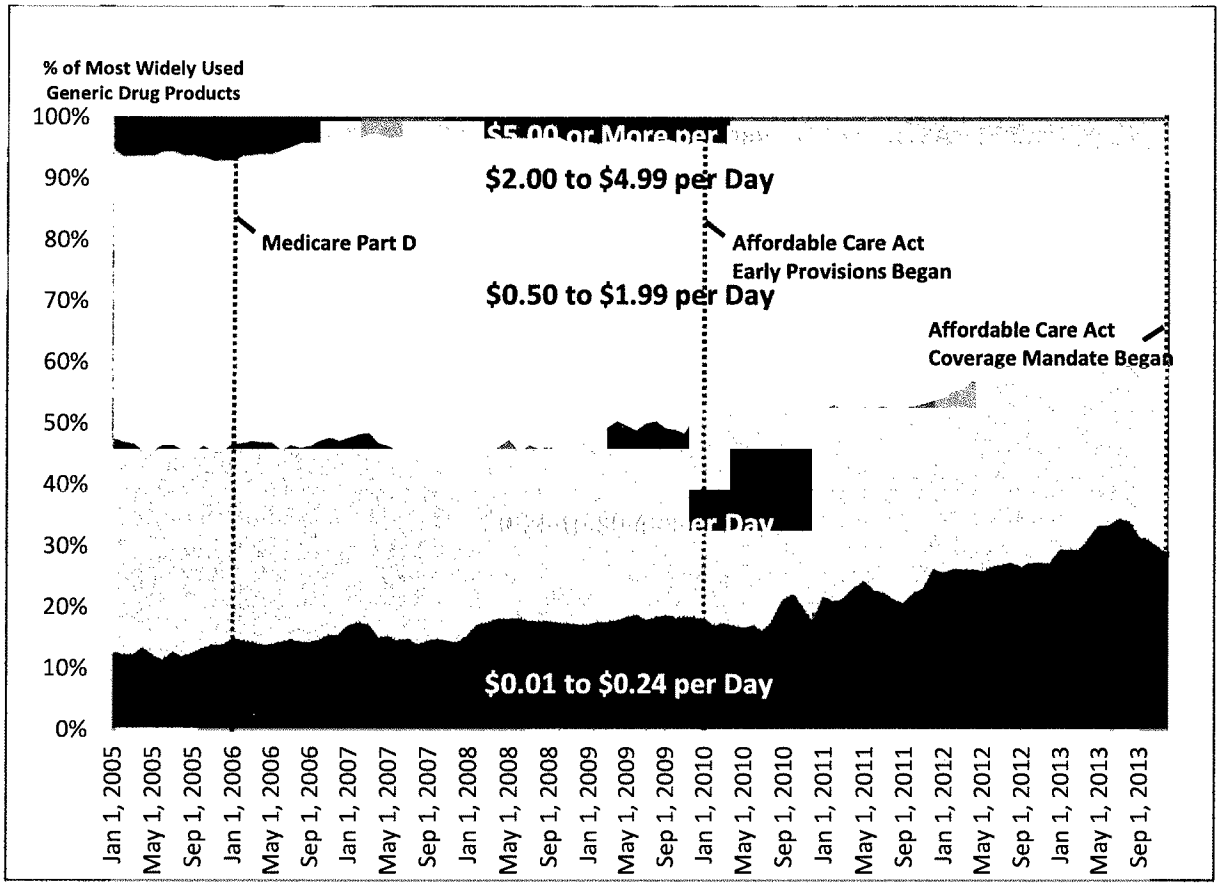
The generic market basket included 280 drug products widely used by older Americans. Nearly one-third (32.5%) of these generic drug products (91 of 280 drug products) had an annual price increase rather than a price decrease in 2013 (i.e., December 31, 2013 versus December 31,

[20] L.S. Rotenstein, N. Ran, J.P. Shivers, M. Yarchoan, and K..L. Close, "Opportunities and Challenges for Biosimilars: What's on the Horizon in the Global Insulin Market?" *Clinical Diabetes*, Vol. 30(4) (2012): 138-150.

2012). Fifty-four (about 20%) generic drug products had an increase of 15% or more in 2013 and twenty-seven (about 10%) generic drug products had an increase of 50% or more in 2013. This market basket was based on outpatient prescription drugs widely used by older Americans. A list of the generic drug products with price increases in 2013 is attached as Appendix A.

More than one-half of the widely used generic drug products had an average cost per day of therapy of less than $0.50. (See Figure 4). The good news is that the number of lower cost generics has increased. And, the bad news is, as noted above, that one-third of the widely used generic drugs products had price increases.

Figure 4. Percent of Generic Drug Products by Retail Price per Day of Therapy: (December 31, 2012 vs. December 31, 2013)



Expected Generic Drug Price Trends. The importance of A-rated generic competition can hardly be overstated. Since the FDA has determined that A-rated generics are identical in all material respects ("pharmaceutically equivalent" and "bioequivalent," and thus "therapeutically equivalent") to a particular brand name drug and these generics can therefore be substituted for the brand name drug by the pharmacist (unless explicitly prohibited) without the intervention of the physician. When a consumer presents a brand name prescription to a pharmacist, mandatory and permissive state drug substitution laws (present in all U.S. states and territories) allow, encourage, and often require the pharmacist to substitute an FDA-approved, A-rated generic version for the brand name drug prescribed. Effective price competition for drug products within a drug molecule market, does not typically begin until substitutable, A-rated generic versions of that same molecule enter the market. FDA-approved, A-rated generics typically are priced substantially below their brand name counterparts. Once an A-rated generic enters the market unimpeded, a large share of purchases of the brand to which the generic is A-rated switches to the generic almost instantaneously, because the generic is identical to the brand, substantially less-expensive, and easily and routinely substitutable by the pharmacist without the intervention of the physician.

Both the price differential between the brand and its A-rated generic equivalents, and the proportion of the market for the "molecule" (typically the brand and its A-rated generic equivalents) captured by the A-rated generics, generally increase rapidly over time, and follow a predictable pattern. This pattern has been extensively studied and is generally accepted as an inherent feature of the pharmaceutical industry.[21]

The prices of A-rated generic drugs drop even further as additional generic competitors for a given drug molecule enter the market. The first A-rated generic competitor generally prices at a level of approximately 15% to 25% below the brand name price. As more A-rated generic products enter into the market, the prices of generics typically continue to decline both in absolute terms and in relation to the brand name price, a trend that typically persists for five years, or more. Generic prices eventually reach as low as 10% to 20%, if not lower, of the pre-generic entry brand name price when an equilibrium, or market-clearing, price point is finally reached.

When A-rated generic competition is unimpeded, the brand name drug rapidly loses sales because the lower-priced, A-rated generic(s) are being routinely substituted by pharmacists, often with the encouragement of private and public managed care organizations (through which more than 85% of prescriptions in the U.S. now flow). There are two primary mechanisms by which managed care organizations encourage A-rated generic substitution: (1) by establishing a lower member copay for A-rated generic drug products; and, (2) by setting a maximum allowable cost (MAC) for the drug product reimbursement that pharmacies will be paid for A-rated generic drug products.

[21] See footnote 10.

Observed Generic Drug Price Trends in 2013. The pattern of generic drug prices over time for the widely used drug products in the 2013 market basket was examined at the individual drug product level. First, we found that there were a number of generic drug products whose prices performed as expected in the market. That is, the generic drug product enters the market at a price 10% to 25% below the brand name price and then the generic price rapidly declines over time until a market leveling price is reached. For example, Figure 5 show Tamsulosin 0.4 mg capsules which entered the market with an actual retail transaction price[22] of about $3.55 per day of therapy (16% below the AWP) and the price rapidly declined to under $0.50 per day or about 10% of the AWP (average wholesale price—a list price) and very close to the WAC (wholesale acquisition price—another benchmark price). A number of the widely used generic drug products had this expected pricing pattern.

A variant on the expected generic pricing pattern was also observed for generic drug products that had some form of formal or functional exclusivity in the market from one or more of the following: (1) an FDA granted exclusivity period; (2) entry of an authorized generic licensed from the NDA holder; (3) an FDA granted 180-day generic exclusivity period; (4) an at-risk generic launch while a patent challenge is on-going in the courts; (5) a pay-for-delay generic situation; or (6) other reasons for delay of more than one true generics entering the market. For example, see Figure 6 (Sertraline HCl 50 mg tablets, Greenstone). This generic entered the market and was able to hold near its entry level price for about 6 months. In this case, the generic sertraline is marketed by Greenstone, which is a generic firm affiliated with Pfizer—the original marketer of the brand version of sertraline known as Zoloft.

A second example of delayed generic competition can be seen in Figure 7 (Pantoprazole Sodium 40 mg tablet DR, Teva Pharmaceuticals). The delay in generic price competition for this drug product was secondary to the at-risk launch of several generic versions before the patent had expired and during the time in which the patent challenge was on-going in the courts. Note that the delay in effective price competition was about three years (Dec. 2007 to Jan. 2011). Once, the challenged patent did expire; then, the typical rapid price decline expected from generic drug products was observed.

There were several generic drug products whose price rose over time after generic entry. See Figures 8, 9 and 10. The generic drug products presented in these figures include an oral suspension, an ophthalmic solution, and a delayed release tablet formulation. In many ways the price pattern of these generic drug products exhibits the traits commonly seen for a brand name drug product. Often generic drug products that are unique dosage forms (e.g., oral liquids; topical ointments, creams, and patches; ophthalmic products; injectable products; or other unique dosage forms) will have pricing behavior like a brand name drug product. Even though a generic drug product market for oral solid dosage forms (i.e., tablets or capsules) may be able to support entry of several generic firms, the market demand for these more unusual dosage forms is often quite limited and may only be able to support one firm in the market. Consequently, the one firm in the

[22] See footnote 15.

market may be able to function as if it had market exclusivity, even though it does not formally have any exclusivity. This functional market exclusivity may allow a generic drug product to raise its price at one point in time or over time.

As noted earlier, nearly 20% (27 of 280) of the widely used generic drug prices saw an annual price increase of 50% or more in 2013. At the top of the list of generic drug products with extraordinary price increases were doxycycline hyclate 100 mg capsules (West-Ward) (see Figure 11) and doxycycline 100 mg tablets (West-Ward) with annual increases of 2,048% and 1,897%, respectively in 2013. One strategy to thwart generic substitution is to change the dosage form (i.e., tablet to capsule, or tablet to tablet extended release), since different dosage forms of the same drug molecule cannot be substituted without the doctors express written permission.

Other generic drug products with extremely high annual price hikes in 2013 were: digioxin 0.125 mg tablets (Lannett) (Figure 12) with an increase of 103% and digioxin 0.25 mg tablets (Lannett) with an increase of 82%; divalproex sodium 500 mg tablets (Mylan) (Figure 13) with an increase of 432%; prednisolone acetate suspension 1% suspension (Sandoz) (Figure 14) with an increase of 349%; levothyroxine sodium at 9 different strengths (Mylan) (Figure 15) with annual increases ranging from 44% to 63%; and glipizide 5 mg tablets (Mylan) (Figure 16) with an increase of 94%. Not all of the large price increases among the widely used generic drug products occurred in 2013. For example, hydralazine HCl 50 mg tablets (Par) (Figure 17) and meclizine HCl 25 mg tablets (Par) (Figure 18) each had increases of more than 100% in 2005 and 2008, respectively.

While there are a number of generic drug products with very large price increases, this is not a new phenomenon. In July of 2008, I prepared a report for the joint Economic Committee of Congress that was presented by my colleague (Madeline M. Carpinelli). This report titled "Extraordinary Price Increases in the Pharmaceutical Market."[23] In this report, we identified drug products that had experienced one or more "extraordinary" price increases.[24] Our study of 35,143 drug products (at the NDC level) found that 13.5% of them had experienced one or more extraordinary price increases in the period 1988 to 2008. While a few of these extraordinary price increases occurred in the 1990s, the vast majority were found in the 2000s.

Clearly, the generic drug product price increases shown in these figures as a red line (the actual retail drug price per day of therapy) were dramatic. These price increases were passed on to the ultimate payer (commercial or government programs) and did increase the amount of their expenditure for these generic prescripitions.

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[23] Madeline M. Carpinelli and Stephen W. Schondelmeyer, Statement on Extraordinary Price Increases in the Pharmaceutical Market, presented to the Joint Economic Committee of the United States Congress, by Madeline M. Carpinelli, PRIME Institute, University of Minnesota, July 24, 2008, 11 pp.

[24] The term "extraordinary" price increase was defined as "any price increase that is equal to, or greater than, 100% at a single point in time.

Signals of Market Failure in the Pharmaceutical Market

The market for drugs does not operate in the same way as most other markets in the United States, where the consumer freely chooses a product. Various aspects of the market for prescription drugs make it unique, including the fact that certain drugs, i.e.., prescription drug products must be prescribed by one set of market players (physicians), dispensed by another market player (pharmacists), paid for by a third-party or market player (employers or the government via insurers or benefit managers, and sometimes partially by the consumer), and then ultimately consumed by the end user (the patient). One must understand and take into account the differing roles of each of these players, in order to understand how competition functions in the market for drugs. The pharmaceutical market possesses institutional structural features and related behaviors that result in an inefficient economic market as evidenced by the unusually large price increases for generic drug products and the extremely high initial prices of brand name drug products.

The marketing of patented, single source drug products in the United States is a very unique market and has a number of atypical structural features. The patent for a drug molecule alone (and other related patents and exclusivities) creates a monopoly for a drug molecule (and related drug products) and will generate sales specifically for that molecule and related drug products, even if there are other similar molecules (and their related drug products) in the same therapeutic class. This unique market structure for pharmaceuticals is due largely to the fact that a prescription must be written by the doctor for a specific drug product and the consumer (patient) is not free to choose the drug product to be purchased, even if there are other drugs in the class that would work as well, or even better. The patient (consumer) must have the doctor's permission slip (i.e., prescription) and the pharmacist must dispense the exact drug product prescribed by the doctor, unless an FDA-approved therapeutically equivalent generic version of the drug product is available on the market—typically as a lower cost substitute.

The choice of the prescription drug product is driven by various types of "directed demand" including physicians who must prescribe the drug product; pharmacy benefit managers (PBMs) who establish formularies and manage networks of pharmacies to dispense prescriptions; pharmacies and pharmacists who must dispense single source drugs when prescribed and who chose the manufacturer source from among available FDA-approved, therapeutically equivalent generic versions of an off-patent drug; insurers and managed care organizations who have risk for providing health care for a prepaid premium; and employers who bear most of the cost for the prescriptions provided to their employees or government programs (e.g., Medicare and Medicaid) who bear most of the cost for the prescriptions provided to the recipients of these programs.

In recent years, the high prices for the new drug therapies has come under criticism for being excessive, unaffordable and unsustainable.[25] The issue of high drug prices has been raised by patients, doctors, health plans, insurers, and by government programs such as Medicare and Medicaid.[26] The various payers for drug therapy are not only complaining about the high price of individual drugs, but they are also beginning to raise concerns about the long term sustainability of the pricing patterns seen for innovative drug therapies.

There has been an explosion of concern (and articles about) very high drug prices for new and, sometimes, innovative drugs introduced in the United States. One recent story in the Wall Street Journal detailed the reaction of physicians at Memorial Sloan Kettering in New York when faced with a new drug whose price was almost double the standard therapy, yet was not appreciably safer or more effective.[27] Not only were the physicians upset by the exorbitant pricing of this new cancer drug, but also private insurers and the federal Medicare program have expressed concerns.[28] In October 2014, "Medicaid chiefs from red and blue states are urging Congress to stem the cost of revolutionary new drugs for hepatitis C, cancer, and other diseases."[29] A recent New York Times editorial argued that "Medicare should consider withdrawing coverage for high-priced cancer drugs that have "modest" benefits.[30] Some have argued that the high prices are needed to fuel the fire of innovation, but others have suggested that "the market is telling us the opposite: that prices have become the prize."[31]

One of the more recent drugs to enter the market at an astronomical price is Sovaldi—used to treat patients with hepatitis C. Solvadi costs about $84,000 per course of therapy in the U.S., while in other countries the price is as low as $900 to $2,000 per course of therapy.[32] Gilead Sciences, the company that markets Sovaldi, had a triple digit rise in profits in early 2014 after introduction of its new drug.[33] Another drug therapy for hepatitis C has just been approved by FDA (October 2014). This new hepatitis C drug, Harvoni, is also marketed by Gilead Sciences and has an even higher price tag--$94,500 for a 12-week course of treatment.[34]

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[25] Lee, Jaimy. Sovaldi fuels triple-digit rises in Gilead revenue and profits. Modern Healthcare. October 28, 2014.; see also, Silverman, Ed. 'Financial Toxicity:' Who's Really to Blame for High Cancer Drug Prices? The Wall Street Journal, October 7, 2014.

[26] Comments on pricing by patients, doctors, health plans, insurers, and by government programs such as Medicare and Medicaid.

[27] Silverman, Ed. 'Financial Toxicity:' Who's Really to Blame for High Cancer Drug Prices? The Wall Street Journal, October 7, 2014.

[28] Herper, Matthew. Could High Drug Prices Be Bad for Innovation? Forbes, Oct. 23, 2014.

[29] Associated Press. States Ask Congress to Intervene on Drug Prices. ABC News. Oct. 26, 2014. Found at this website: http://abcnews.go.com/Health/print?id=26524476 11/.

[30] Howard, Paul. High-Priced Cancer Drugs: Are They Worth It? The New York Times. July 8, 2011.

[31] Herper, Matthew. Could High Drug Prices Be Bad for Innovation? Forbes, Oct. 23, 2014.

[32] Whitman, Debra B., Executive Vice President for Policy, Strategy and International Affairs, AARP. Expensive New Hepatitis C Drug Raises Alarms. Huffington Post, 05/27/2014.

[33] Lee, Jaimy. Sovaldi fuels triple-digit rises in Gilead revenue and profits. Modern Healthcare. October 28, 2014.

[34] Lee, Jaimy. Sovaldi fuels triple-digit rises in Gilead revenue and profits. Modern Healthcare. October 28, 2014.

The high price of Sovaldi has had such a dramatic impact that "many payers and pharmacy benefit managers have begun to push back against Sovaldi's price, with some threatening to stop using the drug once a rival medicine is approved in the United States. State Medicaid directors have also raised concerns, saying that taxpayers will have to shoulder much of Sovaldi's costs since many hepatitis C patients get their health care from the government."[35]

The debate surrounding the price of Sovaldi is part of a much larger issue related to escalating specialty drug prices that are widely viewed as unsustainable. "Specialty drugs now account for 28 percent of total drug spending in the U.S. even though they make up less than 1 percent of all prescriptions."[36]

In fact, high price is the most frequently cited characteristic defining the new class of drugs that we call "specialty drugs."[37] In addition, to being high cost, the specialty drugs also have a high rate of patient cost-sharing. Specialty drugs are placed by commercial and by Medicare Part D plans in a separate "Tier 4" or specialty tier. The specialty tier usually uses a percentage co-insurance rather than a fixed rate coapy.[38] The percentage of coinsurance as a cost share of the total prescription price may range from 20% to 50% and it is not unusual for a specialty prescription to cost $1,000 to more than $50,000 per prescription.

Another new drug in the past few years, Alexion Pharmaceutical's only drug, Soliris, has proved effective at treating the rare disease, atypical Hemolytic Uremic Syndrome (aHUS). This drug therapy has a price tag of one-half a million dollars per patient per year.[39] As the Forbes reporter said, "That's not a typo. By my reckoning Soliris is the priciest drug in the world." (See: Herper, Matthew. The World's Most Expensive Drugs, Forbes, 02-22-10). There are at least nine other drugs on the Forbes list that cost more than $200,000 a year for the average patient who takes them. Most of these very high cost drugs treat rare genetic diseases that afflict fewer than 10,000 patients. Since there are no other therapies for these diseases, the "biotech companies can charge pretty much whatever they want."[40]

The battle over high drug prices is pitting large insurers against the drug companies. "The insurance lobby, America's Health Insurance Plans, has criticized drugmakers for spiraling medicine prices."[41] "Whenever the high price of pharmaceuticals is in the news, drugmakers try desperately to change the subject and distract from the issue," said a spokesman for the insurer lobby. The cost of medication in

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[35] Whitman, Debra B., Executive Vice President for Policy, Strategy and International Affairs, AARP. Expensive New Hepatitis C Drug Raises Alarms. Huffington Post, 05/27/2014.
[36] Whitman, Debra B., Executive Vice President for Policy, Strategy and International Affairs, AARP. Expensive New Hepatitis C Drug Raises Alarms. Huffington Post, 05/27/2014.
[37] EMD Serono Specialty Digest™, 10th Edition, Managed Care Strategies for Specialty Pharmaceuticals, 2014, p. 10.
[38] EMD Serono Specialty Digest™, 10th Edition, Managed Care Strategies for Specialty Pharmaceuticals, 2014, p. 10.
[39] Herper, Matthew. $500,000-A-Year Drug Is Bright Light for Phrma. Forbes. Oct. 21, 2010.
[40] Herper, Matthew. $500,000-A-Year Drug Is Bright Light for Phrma. Forbes. Oct. 21, 2010.
[41] Wayne, Alex. Cancer Patients Assail Insurer Policies on Costly Drugs. Bloomberg. Jun 11, 2014.

the United States might be higher than in other countries where there's negotiated prices and trade agreements,"[42]

New brand name drugs have much higher prices in the United States than in other countries and their prices have been increasing at supra-competitive prices. Brand name drug prices in 2013 increased last year by 21.2%, while brand-name drug use dropped by 15.5%.[43] Given the growing frustration of payers and concern about overall sustainability of drug price levels, at least two major consulting groups have released reports suggesting a new payment model for pharmaceuticals is needed. One of the consulting groups described that "Makers of brand-name pharmaceuticals are competing over a shrinking piece of the prescription drug pie… Several forces are changing the way pharmaceutical companies and other health organizations engage with one another and how they attach value to medications."[44] The second consulting group explained that "It is well established that large pharmaceutical companies tend not to compete on price, particularly in the largest market, the United States (U.S.).[45] The consulting report went on to say, "By competing on price publicly, this would lower the cost of treatment for consumers, while arguably generating greater revenue for the company than received currently for these marginalized agents."[46]

The market for pharmaceuticals appears to be failing when it comes to efficient resource use. The U.S. is the world's largest drug market, yet the U.S. pays the world's highest prices for prescription drugs. The PBMs who manage drug benefit programs for employers often make more revenue from drug manufacturer rebates and other payments than they make from administrative fees fees to their clients (i.e., employers or health plans). This raises serious issues of fiduciary responsibility and conflict of interest. The drug prescribers (i.e., physicians) are not necessarily price-conscious or price-sensitive when it comes to prescribing drugs. Consumers are told to engage in consumer-driven choice of health care, yet the price of prescription drugs is not readily available when the consumer is ready to make a decision about purchasing a prescription. Even if the physician and the consumer want to make price-conscious decisions, the real net cost of prescription drugs is hidden and is not transparent and available.

In summary, the high price of drugs, whether brand name or generic, is a critical issue. Most payers are signaling that they cannot afford the level of resources needed, individually and collectively, to pay for new and innovative therapies at the prices that are being charged. Payers are accustomed to saving money by encouraging patients to appropriately use generic prescriptions. Now these payers are nervous because they see that generic drug prices are increasing by 100's and 1,000's of percents a year. Old generic drugs are being re-purposed

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[42] Wayne, Alex. Cancer Patients Assail Insurer Policies on Costly Drugs. Bloomberg. Jun 11, 2014.
[43] Evans, Melanie. Healthcare prices are up, and patients are buying less. Modern Healthcare, October 28, 2014.
[44] Health Research Institute, PWCHealth. Unleashing value. The changing payment landscape for the US pharmaceutical industry. May 2012
[45] Gorkin, Larry. Time for pharmaceutical companies to compete on price regarding Non-Differentiated ("Me-Too") Drugs. Eye for pharma. 2012.
[46] Gorkin, Larry. Time for pharmaceutical companies to compete on price regarding Non-Differentiated ("Me-Too") Drugs. Eye for pharma. 2012.

therapeutically and their prices are increasing dramatically. These troubling trends in pharmaceutical spending indicate failures in the market for pharmaceuticals. A growing number of observers in the pharmaceutical market are calling for a new approach to pharmaceutical decision-making and to the pricing model for drug therapy.

In other words, the market for pharmaceuticals is out of balance. Prices are not transparent. Without actual price data, it is not possible to make true value-based decisions. Certainly price is not the only issue in a value-based decision, but price is always an issue in value-based decisions. In many ways the pharmaceutical market is very asymmetric—the seller knows a lot more about the product than does the buyer. For example, drug manufacturers know much more about the safety, effectiveness, and cost of their drugs than does the physician, the PBM, the employer, or the consumer. Three Americans received the Nobel prize in economics in 2001 for their work defining the market for lemons.[47] No; their work was not about little yellow fruits, but rather about the market for used cars and the effect of the imbalance in information between the buyer and the seller.[48] Their work found that markets don't work when there is asymmetry of information—that is, when the seller knows a lot more than the buyer, the seller can take advantage of that buyer. Since then, Joseph Stiglitz and some of his colleagues have developed much further the concepts of asymmetric markets, market signals, and their economic impact. "If there was ever a market that was asymmetric, it is health care and especially pharmaceuticals. The lessons we can learn from these Nobel Prize winners are that: (1) the imperfect markets are not "all-knowing and self-correcting," (2) "imperfect information corrupts markets," (3) "markets, when confronted with imperfections, may not be the best way to allocate resources," and (4) "government must play a strong role in a market system, to prevent damage from imperfect information."[49]

Policymakers and legislators continue to call health care a market—and in one sense health care is a market; however, health care is replete with imperfect information. While health care has some structural features that appear to be a market, the information in this market is very asymmetric. With so much 'imperfect information' throughout health care, efficient and effective policy decisions will not necessarily follow. We must recognize and address the issues of imperfect information in health care and assure that accurate, transparent, and useful information is available in the market in order for more effective market-based decisions to be made.

The advice of the Nobel Prize winners is that "government must play a strong role in an imperfect market." Government doesn't have to run or dominate health care, but government has to set the rules for the game to correct for the many types of imperfect information. Government has to put some boundaries on the health care market so that it begins to function like an

[47] Uchitelle, Louis, "3 Americans Awarded Nobel for Economics," The New York Times, October 11, 2011.
[48] Akerlof, George, "The Market for "Lemons": Quality Uncertainty and the Market Mechanism," The Quarterly Journal of Economics, Vol. 84, No. 3 (Aug., 1970), pp. 488-500, Oxford University Press, URL: http://www.jstor.org/stable/1879431.
[49] Louis Uchitelle, "3 Americans Awarded Nobel for Economics," The New York Times, October 11, 2001.

economically efficient market again. Finally, the health care market is very asymmetric for a whole lot of reasons, such as the isolating effect of directed demand, and the insulating effect of insurance coverage. Insurance is a great thing, but in some ways it takes away the market function. Health insurance programs give the appearance of having a fairly low cost when one only focuses on the amount of copays made at the time of service. The consumer only sees the impact of the full cost of their health care a year later when the premiums increase, or when the employer does not provide a wage increase because health care cost went up.

There are many forms of imperfect information about prescription drugs including, but not limited to, hidden prices, rebates, and discounts; undisclosed relationships and transactions; and complex technical products. This imperfect information may inhibit, or even prevent, value-based decisions at every level of the pharmaceutical market.

Conclusions

The prices and change in prices of both brand name and generic drug products have a direct impact on the costs borne by individual consumers and by all other payers. Brand name and generic drug price increases often result in higher out-of-pocket costs for beneficiaries at the pharmacy, especially for those who pay a percentage of drug costs rather than a fixed copayment. Higher brand name and generic drug prices are also passed along to consumers, or the end payer, in the form of increased premiums, higher deductibles, and other forms of cost sharing.[50]

Prescription drug price increases also affect taxpayer-funded programs like Medicare and Medicaid. For example, the Medicare Payment Advisory Commission recently attributed the majority of "excess" growth in Medicare Part D spending to growth in the average price of drugs provided to beneficiaries. Higher government spending driven by large drug price increases will eventually affect all Americans in the form of higher taxes, cuts to public programs, or both. If recent trends for brand name and generic drug prices and related price increases continue unabated, the cost of drugs will prompt increasing numbers of older Americans to stop taking necessary medications.[51] This will lead to poorer health outcomes and higher health care costs in the future.[52]

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[50] D.I. Auerbach and A.L. Kellermann, "A Decade of Health Care Cost Growth Has Wiped Out Real Income Gains for an Average U.S. Family," *Health Affairs*, Vol. 30(9) (2011): 1630-1636.

[51] H. Naci, S.B. Soumerai, D. Ross-Degnan, F. Zhang, B.A. Briesacher, J.H. Gurwitz, and J.M. Madden , "Medication Affordability Gains Following Medicare Part D Are Eroding among Elderly with Multiple Chronic Conditions," *Health Affairs*, Vol. 33(8) (2014): 1435-1443.

[52] Z.A. Marcum, M.A. Sevick, and S.M. Handler, "Medication Nonadherence A Diagnosable and Treatable Medical Condition," *Journal of the American Medical Association*, Vol. 309(20) (2013): 2105-2106.

The expansion of health care and prescription drug coverage has provided more Americans with access to important and valuable drug therapies. Given the expansion of the number of people with coverage for prescription drugs,[53] without effective measures to evaluate and manage the appropriateness, utilization, and price of drug therapies—Congress has essentially written a blank check to the pharmaceutical firms. It is unclear what factors are driving the price levels and the continued price increases of brand name and generic prescription drugs. Policy makers interested in reducing the impact of brand name and generic prescription drug prices should focus on options that balance the need for pharmaceutical innovation with the need for improved health and the financial security of consumers and taxpayer-funded programs like Medicare and Medicaid.

[53] A.M. Sisko, S.P. Keehan, G.A. Cuckler, A.J. Madison, S.D. Smith, C.J. Wolfe, D.A. Stone, J.M. Lizonitz, and J.A. Poisal , "National Health Expenditure Projections, 2013-23: Faster Growth Expected with Expanded Coverage and Improving Economy," *Health Affairs*, Vol. 33(10) (2014): 1-10.

Appendix A
Actual Transaction Price Changes at the Retail Level for Widely Used Generic Drugs in 2013
(December 31, 2012 vs. December 31, 2013)

D	F	G	H	I	J	O	T	T	T
National Drug Code	Generic Name	Dose Form	Strength		Manufacturer	Usual Dose/ Day	Retail $/Day (Median)	Retail $/Day (Median)	% Change from Same Mo. In Previous Yr.
							2012 (Dec. 31)	2013 (Dec. 31)	2013 v 2012
00143-3142-05	doxycycline hyclate	Capsule	100	MG	West-Ward	2.00	$ 0.34746	$ 7.46247	2047.7%
00143-2112-05	doxycycline hyclate	Tablet	100	MG	West-Ward	2.00	$ 0.36154	$ 7.21887	1896.7%
00378-0473-01	divalproex sodium	Tablet ER 24 Hr	500	MG	Mylan	2.00	$ 1.01462	$ 5.39401	431.6%
61314-0637-10	prednisolone acetate	Suspension	1	%	Sandoz	0.33	$ 0.56934	$ 2.55771	349.2%
00378-0014-01	methotrexate sodium	Tablet	2.5	MG	Mylan	1.00	$ 0.74336	$ 2.67062	259.3%
00603-4975-28	oxybutynin chloride	Tablet	5	MG	Qualitest	2.00	$ 0.23875	$ 0.55005	130.4%
68382-0137-01	losartan potassium	Tablet	100	MG	Zydus Pharmaceuticals (USA)	1.00	$ 0.39322	$ 0.87400	122.3%
00093-8121-01	doxazosin mesylate	Tablet	2	MG	Teva Pharmaceuticals USA	1.00	$ 0.22447	$ 0.47015	109.4%
00172-5412-11	fluconazole	Tablet	150	MG	Ivax Pharmaceuticals	1.00	$ 1.76095	$ 3.58117	103.4%
00527-1324-10	digoxin	Tablet	0.125	MG	Lannett	1.00	$ 0.19652	$ 0.39965	103.4%
00093-7202-98	pravastatin sodium	Tablet	40	MG	Teva Pharmaceuticals USA	1.00	$ 0.26452	$ 0.53696	103.0%
00378-1105-05	glipizide	Tablet	5	MG	Mylan	1.00	$ 0.13780	$ 0.26743	94.1%
00527-1325-10	digoxin	Tablet	0.25	MG	Lannett	1.00	$ 0.21161	$ 0.38406	81.5%
55111-0180-15	tizanidine HCl	Tablet	4	MG	Dr. Reddy's Laboratories	2.52	$ 0.50050	$ 0.88140	76.1%
00143-1473-10	prednisone	Tablet	10	MG	West-Ward	3.00	$ 0.31398	$ 0.54257	72.8%
00093-7201-98	pravastatin sodium	Tablet	20	MG	Teva Pharmaceuticals USA	1.00	$ 0.26420	$ 0.44680	69.1%
00093-7270-98	pravastatin sodium	Tablet	80	MG	Teva Pharmaceuticals USA	1.00	$ 0.46336	$ 0.77111	66.4%
00378-1817-01	levothyroxine sodium	Tablet	175	MCG	Mylan	1.00	$ 0.27772	$ 0.45403	63.5%
00093-8122-01	doxazosin mesylate	Tablet	4	MG	Teva Pharmaceuticals USA	1.00	$ 0.22254	$ 0.36244	62.9%
64679-0926-02	enalapril maleate	Tablet	20	MG	Wockhardt USA	1.00	$ 0.13414	$ 0.21386	59.4%
00378-1805-01	levothyroxine sodium	Tablet	75	MCG	Mylan	1.00	$ 0.22007	$ 0.34504	56.8%
00591-0932-01	oxycodone w/acetaminophen	Tablet	10-325	MG	Watson Labs	5.00	$ 2.51581	$ 3.92472	56.0%
00378-1110-05	glipizide	Tablet	10	MG	Mylan	2.00	$ 0.20166	$ 0.31260	55.0%
00378-1809-01	levothyroxine sodium	Tablet	100	MCG	Mylan	1.00	$ 0.22422	$ 0.34703	54.8%
00378-1807-01	levothyroxine sodium	Tablet	88	MCG	Mylan	1.00	$ 0.22853	$ 0.34932	52.9%
00378-1819-01	levothyroxine sodium	Tablet	200	MCG	Mylan	1.00	$ 0.29933	$ 0.45710	52.7%
00378-1811-01	levothyroxine sodium	Tablet	112	MCG	Mylan	1.00	$ 0.25125	$ 0.38077	51.6%
00378-1815-01	levothyroxine sodium	Tablet	150	MCG	Mylan	1.00	$ 0.26280	$ 0.39359	49.8%
00378-1813-01	levothyroxine sodium	Tablet	125	MCG	Mylan	1.00	$ 0.25031	$ 0.36775	46.9%
00406-0512-01	oxycodone w/acetaminophen	Tablet	5-325	MG	Mallinckrodt Pharm	6.00	$ 1.01691	$ 1.48719	46.2%
00378-5222-93	omeprazole	Capsule DR	40	MG	Mylan	1.00	$ 0.54705	$ 0.78619	43.7%
00378-1800-01	levothyroxine sodium	Tablet	25	MCG	Mylan	1.00	$ 0.18659	$ 0.26770	43.5%
00591-5443-01	prednisone	Tablet	20	MG	Watson Labs	2.00	$ 0.37382	$ 0.51585	38.0%
00093-0771-98	pravastatin sodium	Tablet	10	MG	Teva Pharmaceuticals USA	1.00	$ 0.29679	$ 0.40647	37.0%
00172-4280-60	verapamil HCl	Tablet ER	240	MG	Ivax Pharmaceuticals	1.00	$ 0.39671	$ 0.54330	37.0%
00378-1803-01	levothyroxine sodium	Tablet	50	MCG	Mylan	1.00	$ 0.23054	$ 0.31536	36.8%
00228-2057-50	lorazepam	Tablet	0.5	MG	Actavis Elizabeth	2.00	$ 0.22872	$ 0.30826	34.8%
00378-2146-05	spironolactone	Tablet	25	MG	Mylan	1.00	$ 0.26174	$ 0.34602	32.2%
59762-0246-01	donepezil hydrochloride	Tablet	10	MG	Greenstone	1.00	$ 0.41614	$ 0.54200	30.2%
00378-1355-05	triamterene & HCTZ	Tablet	75-50	MG	Mylan	1.00	$ 0.25753	$ 0.33449	29.9%
64679-0925-02	enalapril maleate	Tablet	10	MG	Wockhardt USA	1.00	$ 0.13353	$ 0.16349	22.4%
68180-0211-09	losartan potassium	Tablet	50	MG	Lupin Pharmaceuticals	1.00	$ 0.43096	$ 0.52244	21.2%
00093-0012-98	pantoprazole sodium	Tablet DR	40	MG	Teva Pharmaceuticals USA	1.00	$ 0.44873	$ 0.54185	20.8%
45802-0064-05	triamcinolone acetonide	Cream	0.1	%	Perrigo Pharmaceuticals	15.00	$ 0.98104	$ 1.17596	19.9%
68180-0589-01	ramipril	Capsule	2.5	MG	Lupin Pharmaceuticals	1.00	$ 0.35514	$ 0.42522	19.7%
64679-0924-02	enalapril maleate	Tablet	5	MG	Wockhardt USA	1.00	$ 0.13608	$ 0.16240	19.3%
61314-0144-10	brimonidine tartrate	Solution, Ophth	0.15	%	Sandoz	0.33	$ 4.48284	$ 5.32053	18.7%
55111-0158-10	omeprazole	Capsule DR	20	MG	Dr. Reddy's Laboratories	1.00	$ 0.33622	$ 0.39661	18.0%
68180-0468-03	lovastatin	Tablet	20	MG	Lupin Pharmaceuticals	1.00	$ 0.18572	$ 0.21816	17.5%
00591-5782-01	atenolol & chlorthalidone	Tablet	50-25	MG	Watson Labs	1.00	$ 0.18238	$ 0.21382	17.2%
68180-0590-01	ramipril	Capsule	5	MG	Lupin Pharmaceuticals	1.00	$ 0.32890	$ 0.38084	15.8%
00591-0933-01	oxycodone w/acetaminophen	Tablet	7.5-325	MG	Watson Labs	6.00	$ 3.23484	$ 3.74394	15.7%
00378-0032-10	metoprolol tartrate	Tablet	50	MG	Mylan	2.00	$ 0.16079	$ 0.18564	15.5%
68462-0248-05	ranitidine HCl	Tablet	150	MG	Glenmark Pharmaceuticals	2.00	$ 0.25081	$ 0.28839	15.0%
00093-7364-98	losartan potassium	Tablet	25	MG	Teva Pharmaceuticals USA	1.00	$ 0.33840	$ 0.38390	13.4%
00093-0787-01	atenolol	Tablet	25	MG	Teva Pharmaceuticals USA	1.00	$ 0.14570	$ 0.16453	12.9%
00093-0753-01	atenolol	Tablet	100	MG	Teva Pharmaceuticals USA	1.00	$ 0.14344	$ 0.16184	12.8%
00093-1049-01	metformin HCl	Tablet	850	MG	Teva Pharmaceuticals USA	2.00	$ 0.21528	$ 0.24100	11.9%
00378-0047-10	metoprolol tartrate	Tablet	100	MG	Mylan	2.00	$ 0.20293	$ 0.22570	11.2%

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							2012 (Dec. 31)	2013 (Dec. 31)	2013 v 2012
59762-4960-01	sertraline HCl	Tablet	25	MG	Greenstone	1.00	$ 0.21612	$ 0.24020	11.1%
00093-5711-01	glyburide-metformin	Tablet	2.5-500	MG	Teva Pharmaceuticals USA	3.00	$ 0.39331	$ 0.43471	10.5%
00378-0222-01	chlorthalidone	Tablet	25	MG	Mylan	1.00	$ 0.42865	$ 0.47364	10.5%
00093-5126-01	benazepril HCl	Tablet	20	MG	Teva Pharmaceuticals USA	1.00	$ 0.20180	$ 0.22293	10.5%
00093-5127-01	benazepril HCl	Tablet	40	MG	Teva Pharmaceuticals USA	6.00	$ 0.16005	$ 0.17656	10.3%
00093-6816-73	budesonide	Suspension	0.5	MG/2ML	Teva Pharmaceuticals USA	2.00	$ 7.42644	$ 8.10935	9.2%
13668-0010-01	citalopram hydrobromide	Tablet	20	MG	Torrent Pharmaceuticals	1.00	$ 0.13346	$ 0.14555	9.1%
00591-0503-05	hydrocodone-acetaminophen	Tablet	10-650	MG	Watson Labs	4.10	$ 1.03315	$ 1.12119	8.5%
68180-0591-01	ramipril	Capsule	10	MG	Lupin Pharmaceuticals	1.00	$ 0.42357	$ 0.45841	8.2%
00172-2083-80	hydrochlorothiazide	Tablet	25	MG	Ivax Pharmaceuticals	1.00	$ 0.09072	$ 0.09807	8.1%
00115-5522-10	fenofibrate	Tablet	160	MG	Global Pharmaceutical Corp	1.00	$ 1.68611	$ 1.81553	7.7%
59762-5033-01	glipizide	Tablet ER 24 Hr	10	MG	Greenstone	1.00	$ 0.48351	$ 0.52045	7.6%
68180-0501-01	meloxicam	Tablet	7.5	MG	Lupin Pharmaceuticals	1.00	$ 0.16250	$ 0.17479	7.6%
00591-0540-05	hydrocodone-acetaminophen	Tablet	10-500	MG	Watson Labs	6.00	$ 2.08695	$ 2.24364	7.5%
00093-5117-98	diltiazem HCl	Capsule CR 24 Hr	180	MG	Teva Pharmaceuticals USA	1.00	$ 0.66418	$ 0.71179	7.2%
00591-0241-05	lorazepam	Tablet	1	MG	Watson Labs	2.00	$ 0.23162	$ 0.24723	6.7%
68180-0517-03	lisinopril	Tablet	40	MG	Lupin Pharmaceuticals	1.00	$ 0.24411	$ 0.25909	6.1%
00093-5712-01	glyburide-metformin	Tablet	5-500	MG	Teva Pharmaceuticals USA	3.00	$ 0.54643	$ 0.57981	6.1%
00591-0844-01	glipizide	Tablet ER 24 Hr	5	MG	Watson Labs	1.00	$ 0.30863	$ 0.32535	5.4%
00378-0018-01	metoprolol tartrate	Tablet	25	MG	Mylan	2.00	$ 0.17307	$ 0.18151	4.9%
00143-1475-10	prednisone	Tablet	5	MG	West-Ward	1.00	$ 0.08148	$ 0.08508	4.4%
00574-2008-02	nystatin (Nystop)	Powder	100000	UNIT/GM	Paddock	3.99	$ 4.21999	$ 4.40523	4.4%
00172-4096-60	baclofen	Tablet	10	MG	Ivax Pharmaceuticals	3.00	$ 0.25505	$ 0.26388	3.5%
00781-1123-05	triamterene & HCTZ	Tablet	37.5-25	MG	Sandoz	1.00	$ 0.30536	$ 0.31583	3.4%
64720-0321-10	metaxalone	Tablet	800	MG	Corepharma	3.00	$ 10.74831	$ 11.11366	3.4%
00555-0612-14	pramipexole dihydrochloride	Tablet	0.25	MG	Teva Pharmaceuticals USA	1.09	$ 0.32922	$ 0.33768	2.6%
00093-0073-01	zolpidem tartrate	Tablet	5	MG	Teva Pharmaceuticals USA	1.00	$ 0.16205	$ 0.16561	2.2%
00591-0385-05	hydrocodone-acetaminophen	Tablet	7.5-500	MG	Watson Labs	4.00	$ 0.67209	$ 0.68422	1.8%
59762-4910-05	sertraline HCl	Tablet	100	MG	Greenstone	1.00	$ 0.23781	$ 0.24187	1.7%
00603-2115-21	allopurinol	Tablet	100	MG	Qualitest	1.00	$ 0.13313	$ 0.13505	1.4%
00555-0899-02	estradiol	Tablet	0.5	MG	Teva Pharmaceuticals USA	1.00	$ 0.13977	$ 0.14165	1.3%
00093-5171-44	alendronate sodium	Tablet	70	MG	Teva Pharmaceuticals USA	0.14	$ 0.30395	$ 0.30660	0.9%

Appendix B

Actual Transaction Prices at the Retail Level for Widely Used Generic Drugs (January 1, 2005 to December 31, 2013)

Case Studies of Selected Drug Products

Figure 5. Tamsulosin HCl 0.4 mg Capsule (Zydus Pharmaceuticals) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

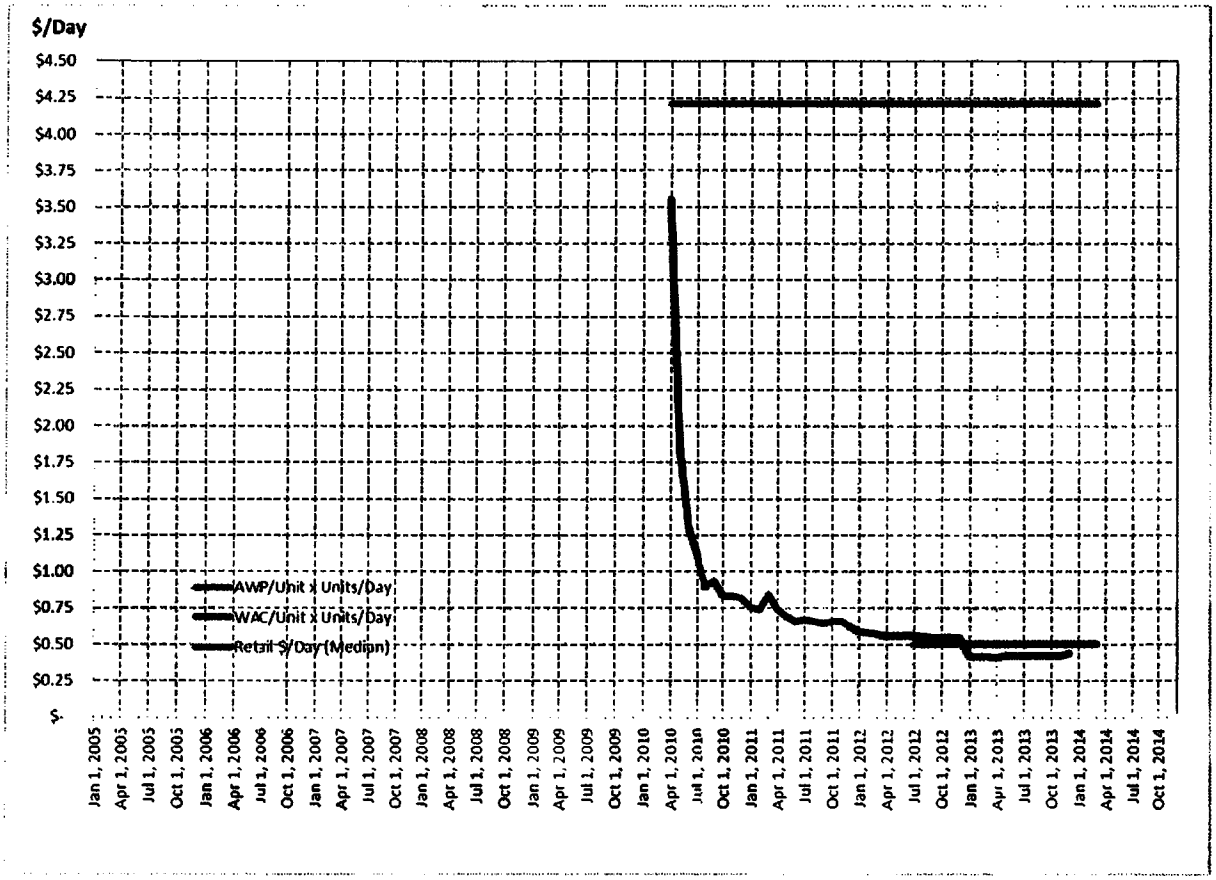


Figure 6. Sertraline HCl 50 mg Tablet (Greenstone) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

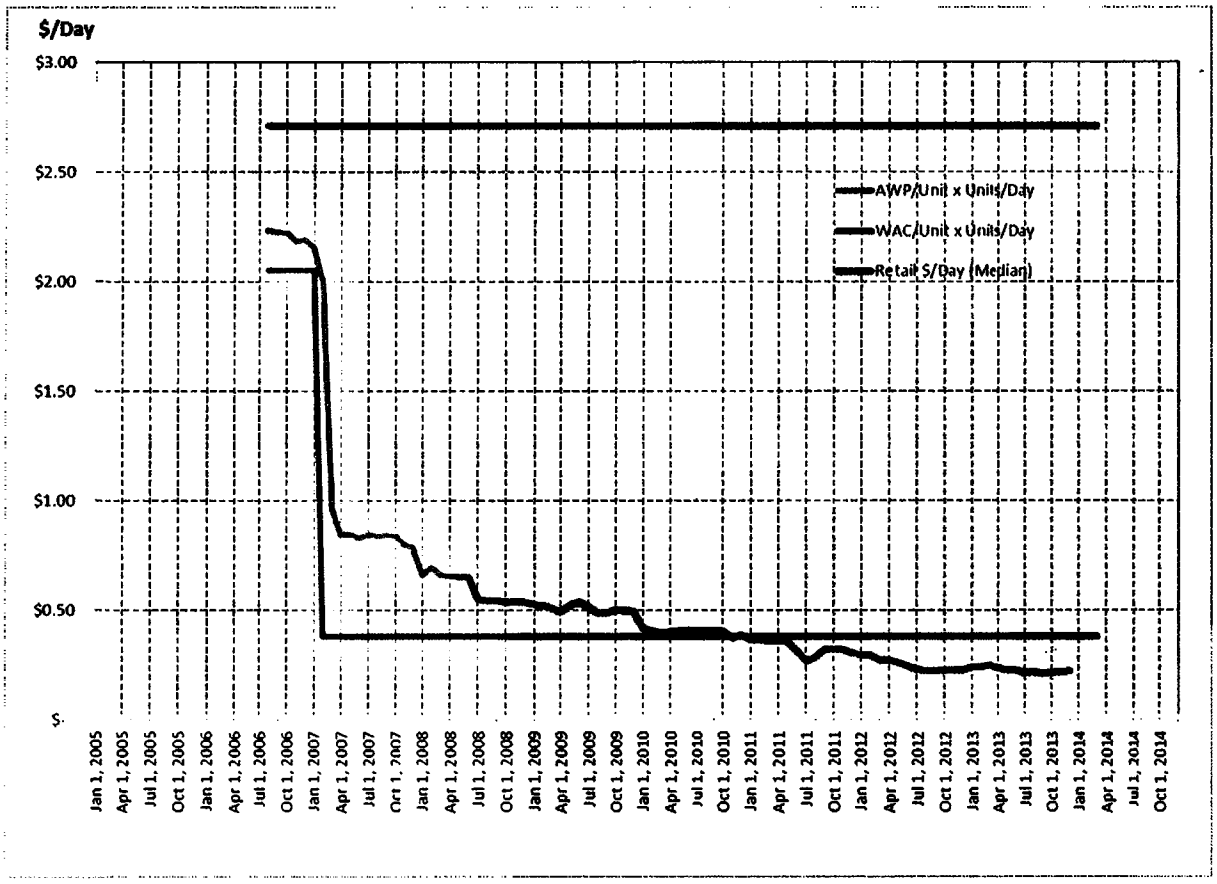


Figure 7. Pantoprazole Sodium 40 mg Tablet DR (Teva Pharmaceuticals) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

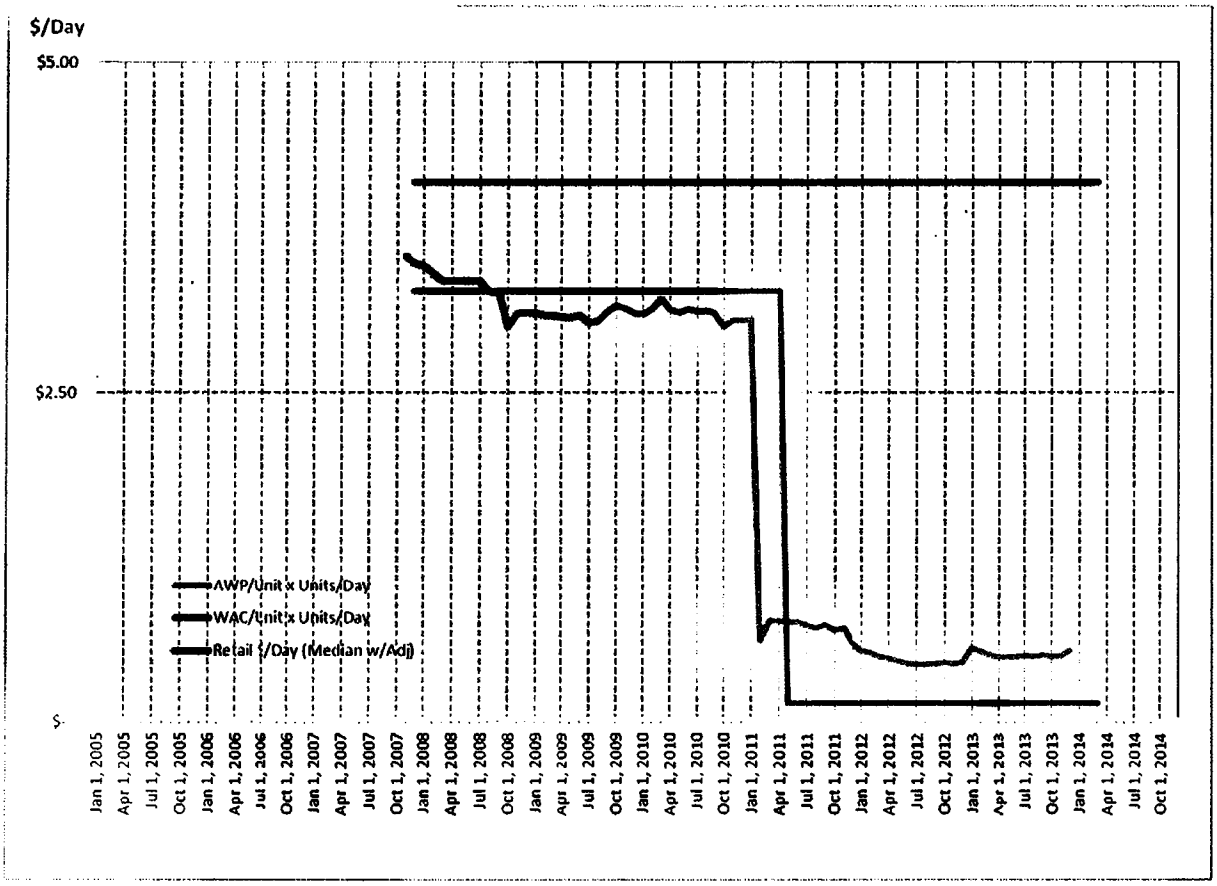


Figure 8. Budesonide 0.5 mg/2ml Suspension (Teva Pharmaceuticals) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

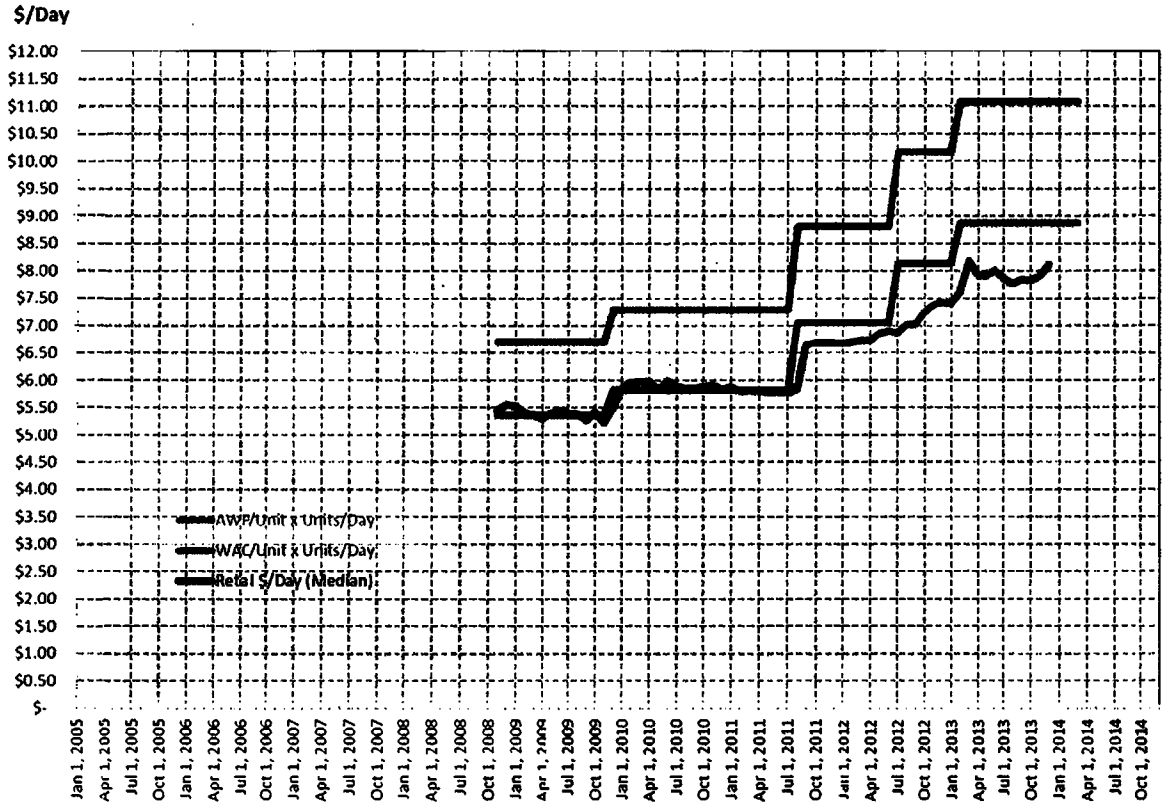


Figure 9. Brimonidine Tartrate 0.15% Ophthalmic Solution (Sandoz) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

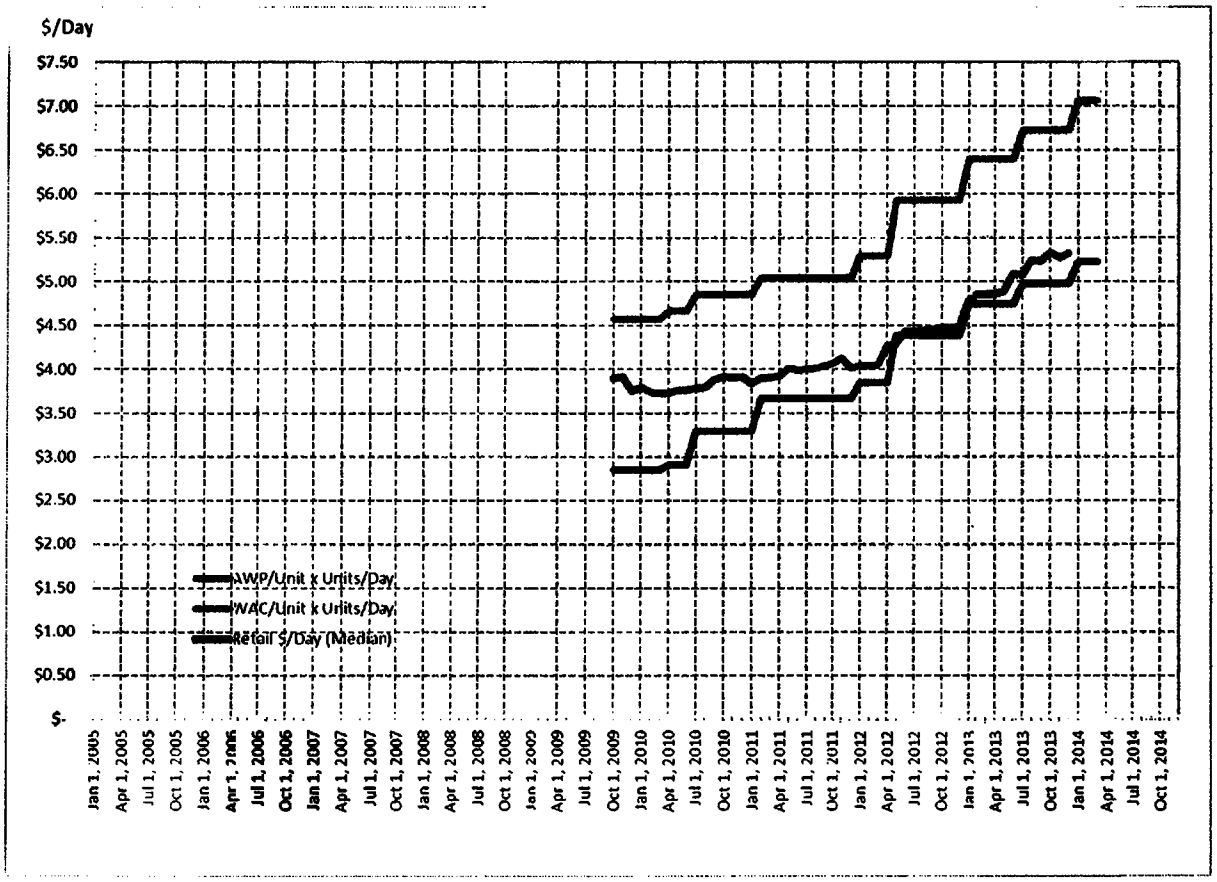


Figure 10. Potassium Chloride 10 MEQ Capsule ER (Watson Labs) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

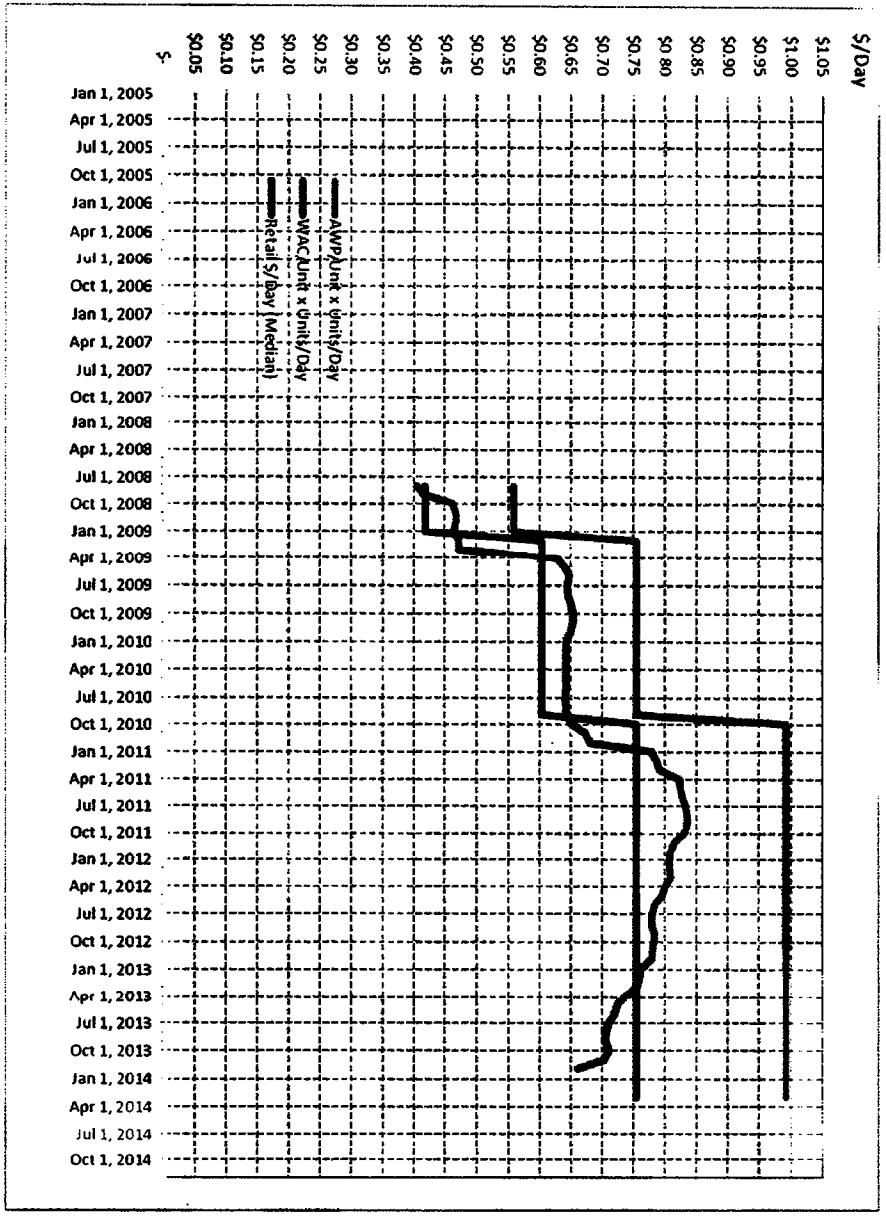


Figure 11. Doxycycline Hyclate 100 mg Capsule (West-Ward) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

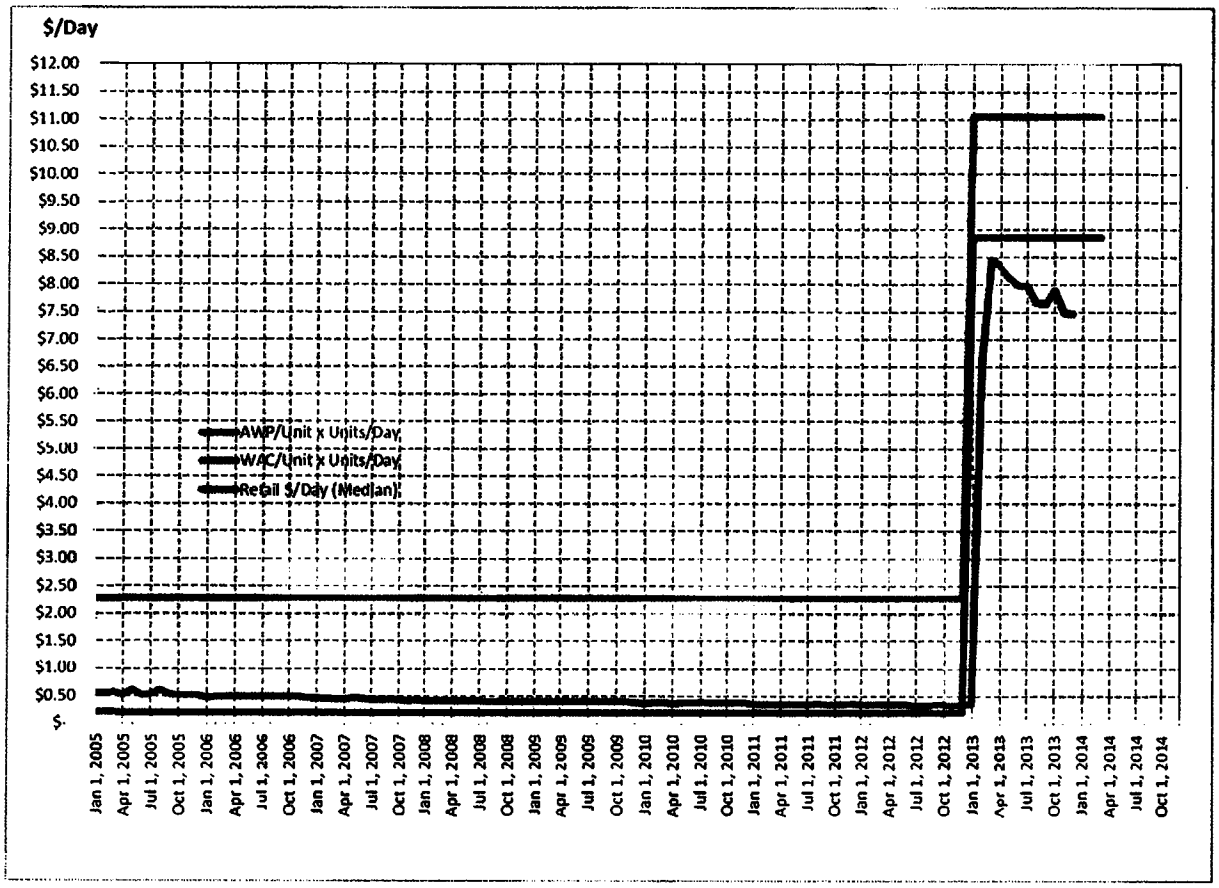


Figure 12. Digoxin 0.25 mg Tablet (Lannett) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

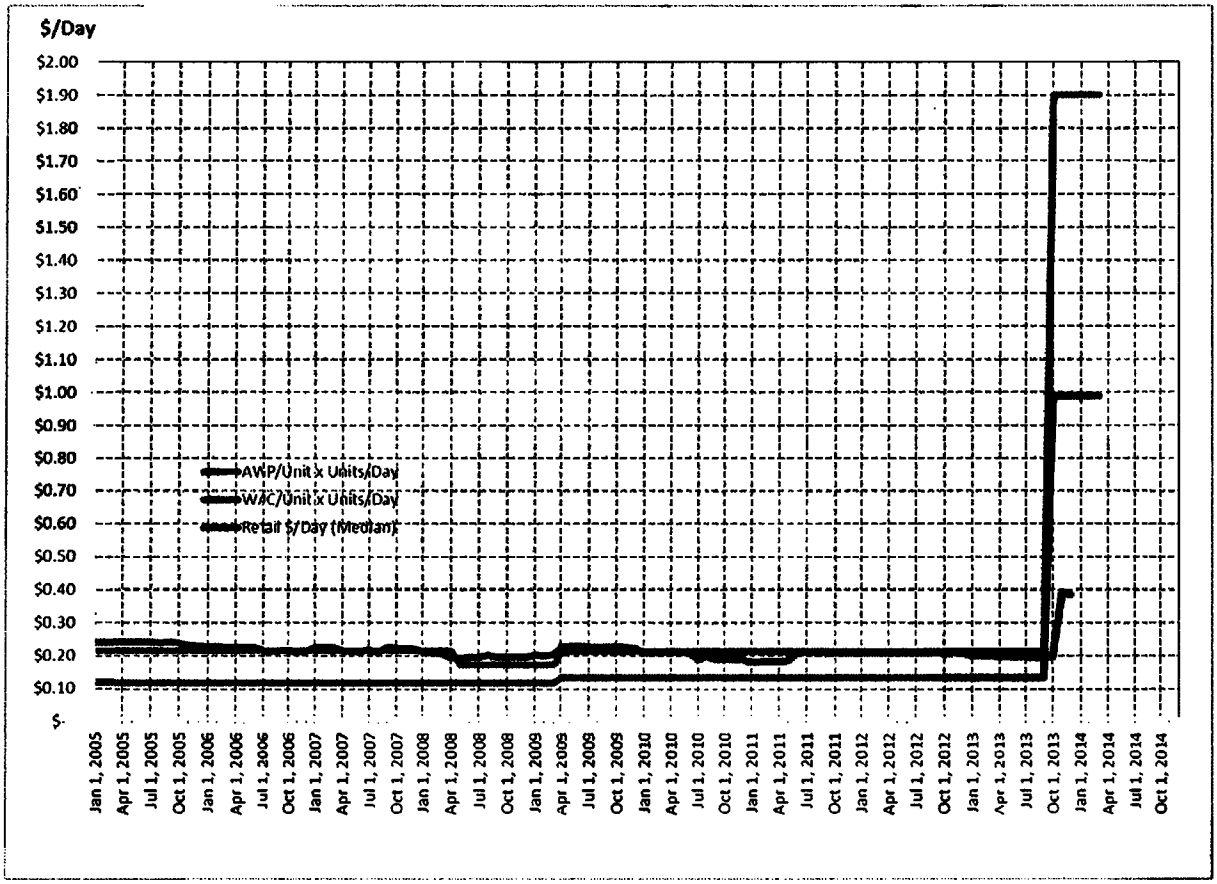


Figure 13. Divalproex Sodium 500 mg Tablet ER 24 Hr (Mylan) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

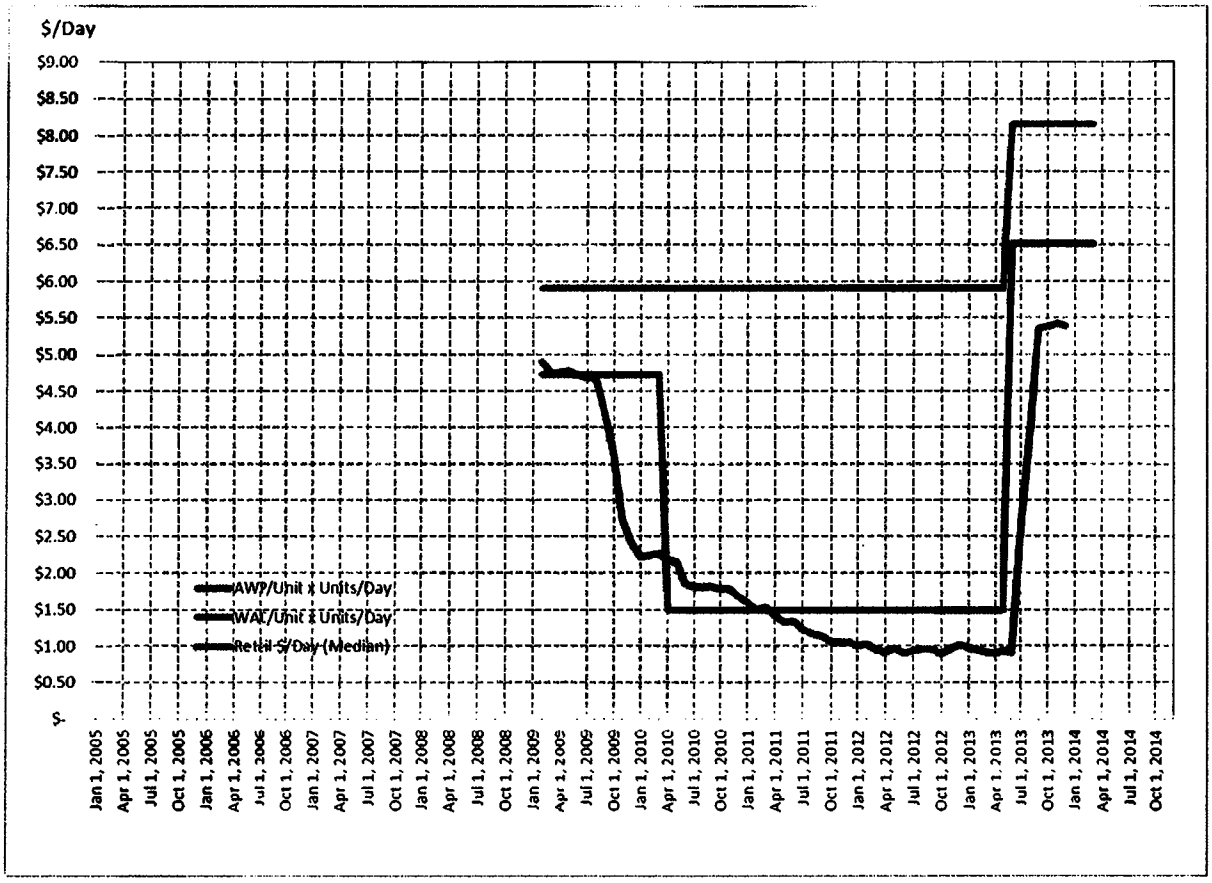


Figure 14. Prednisolone Acetate 1% Suspension (Sandoz) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

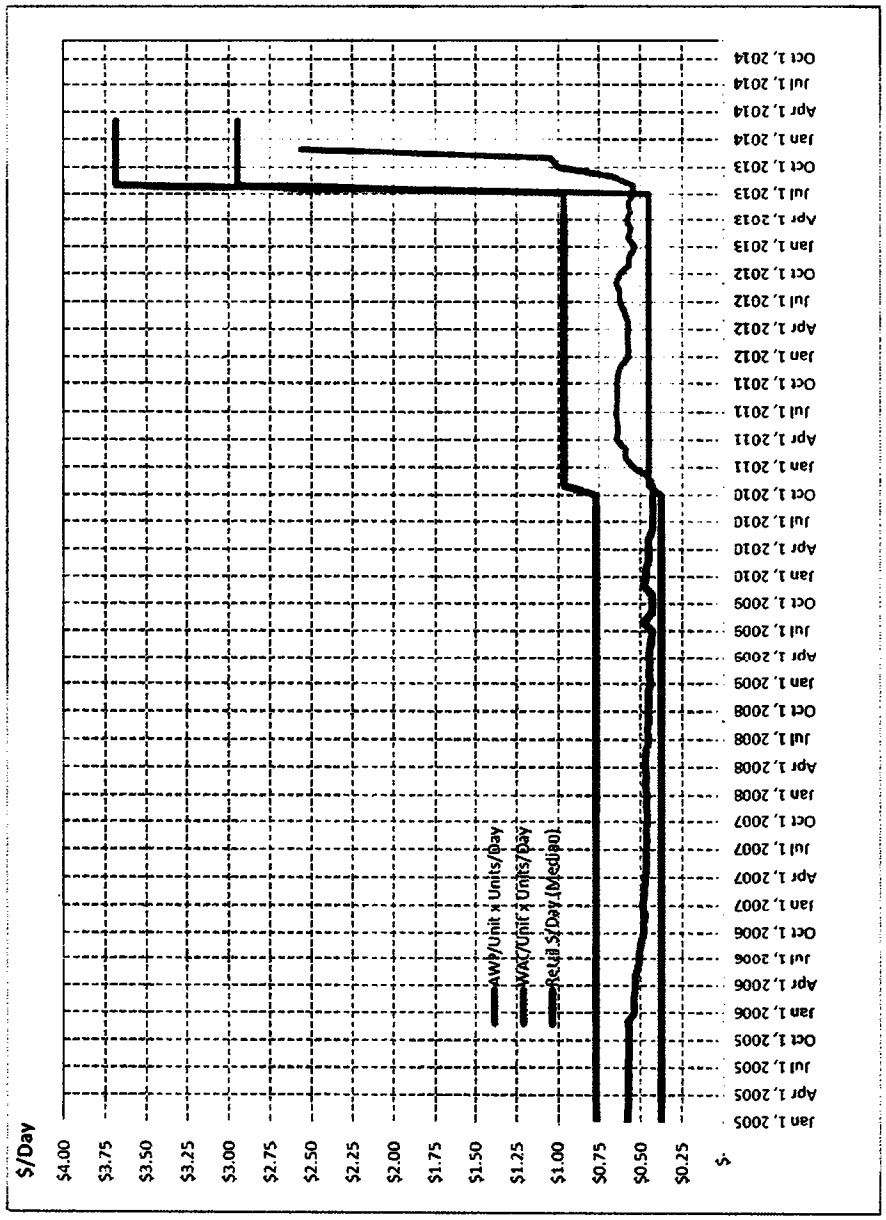


Figure 15. Levothyroxine Sodium 175 mcg Tablet (Mylan) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

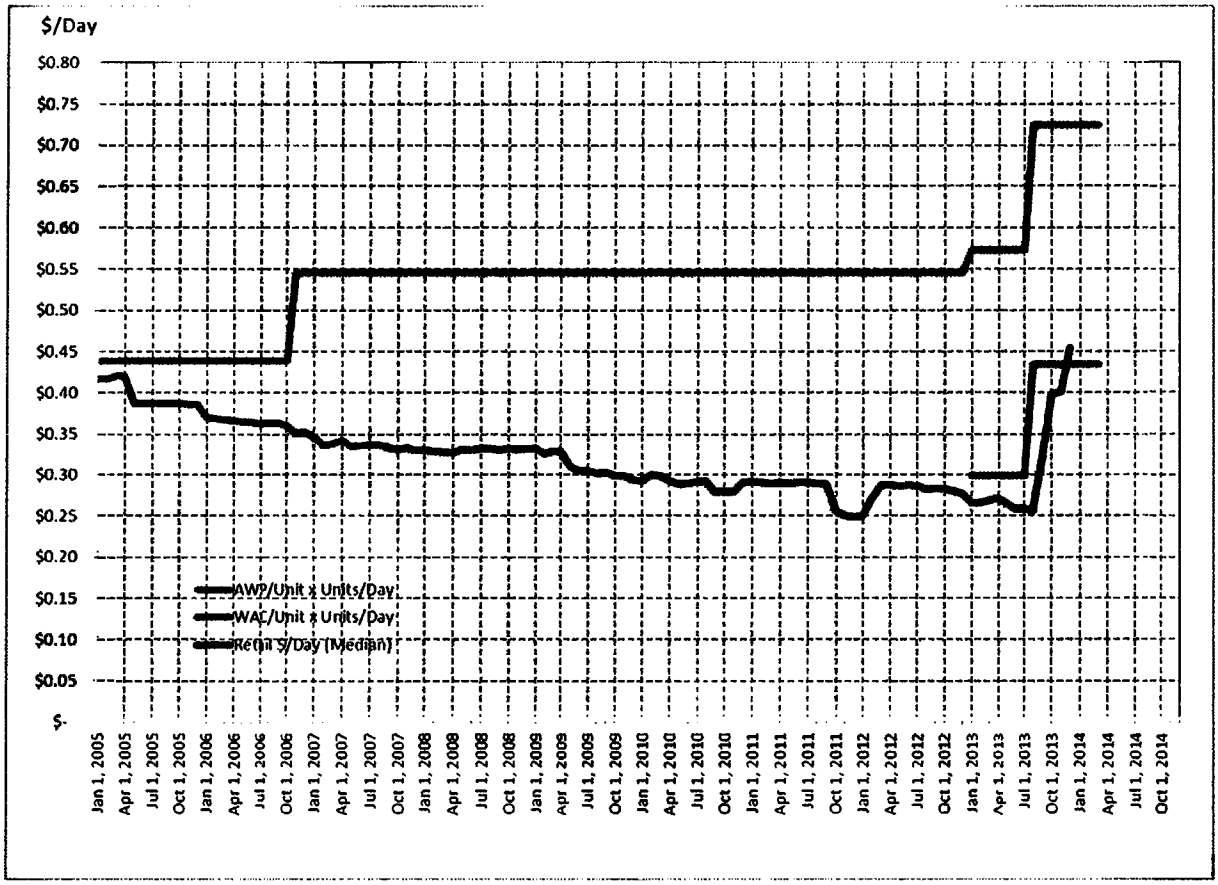


Figure 16. Glipizide 5 mg Tablet (Mylan) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

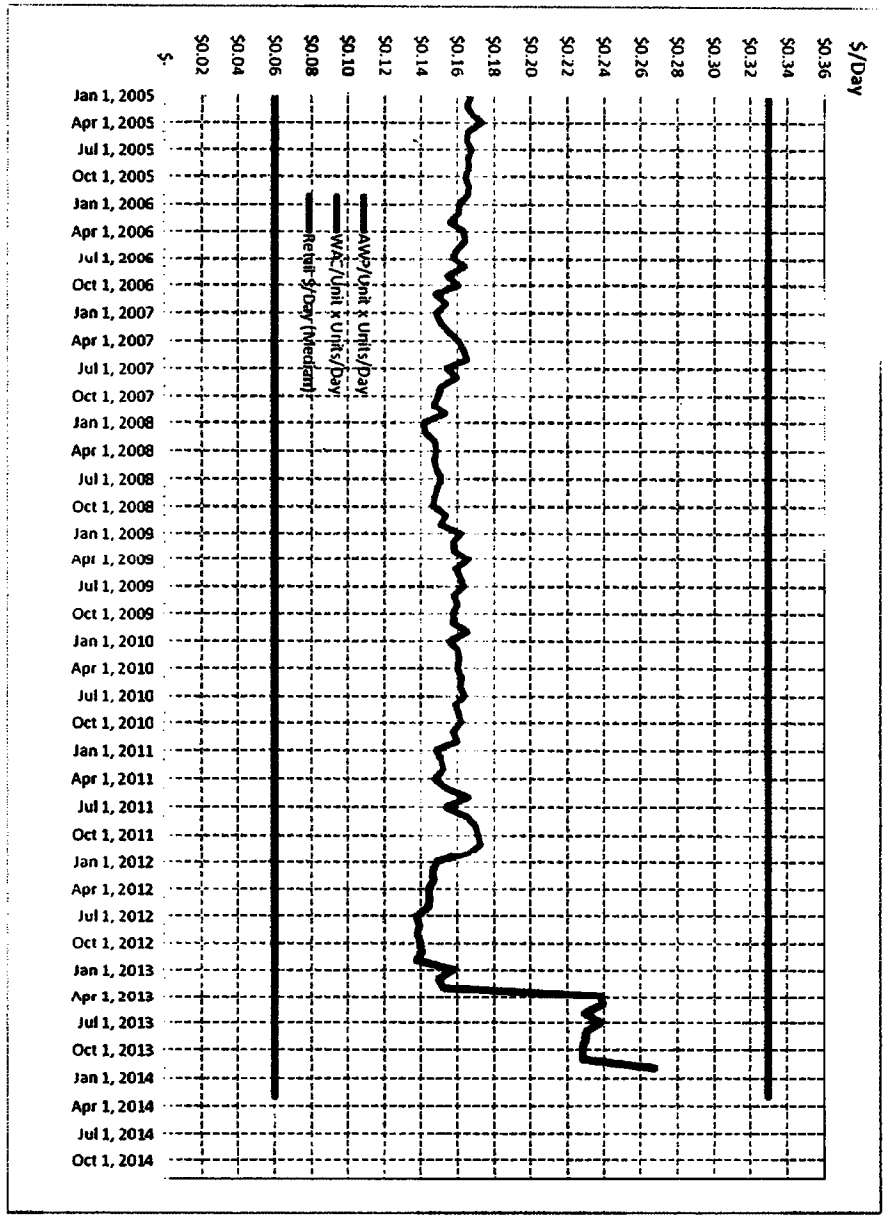


Figure 17. Hydralazine HCl 50 mg Tablet (Par) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

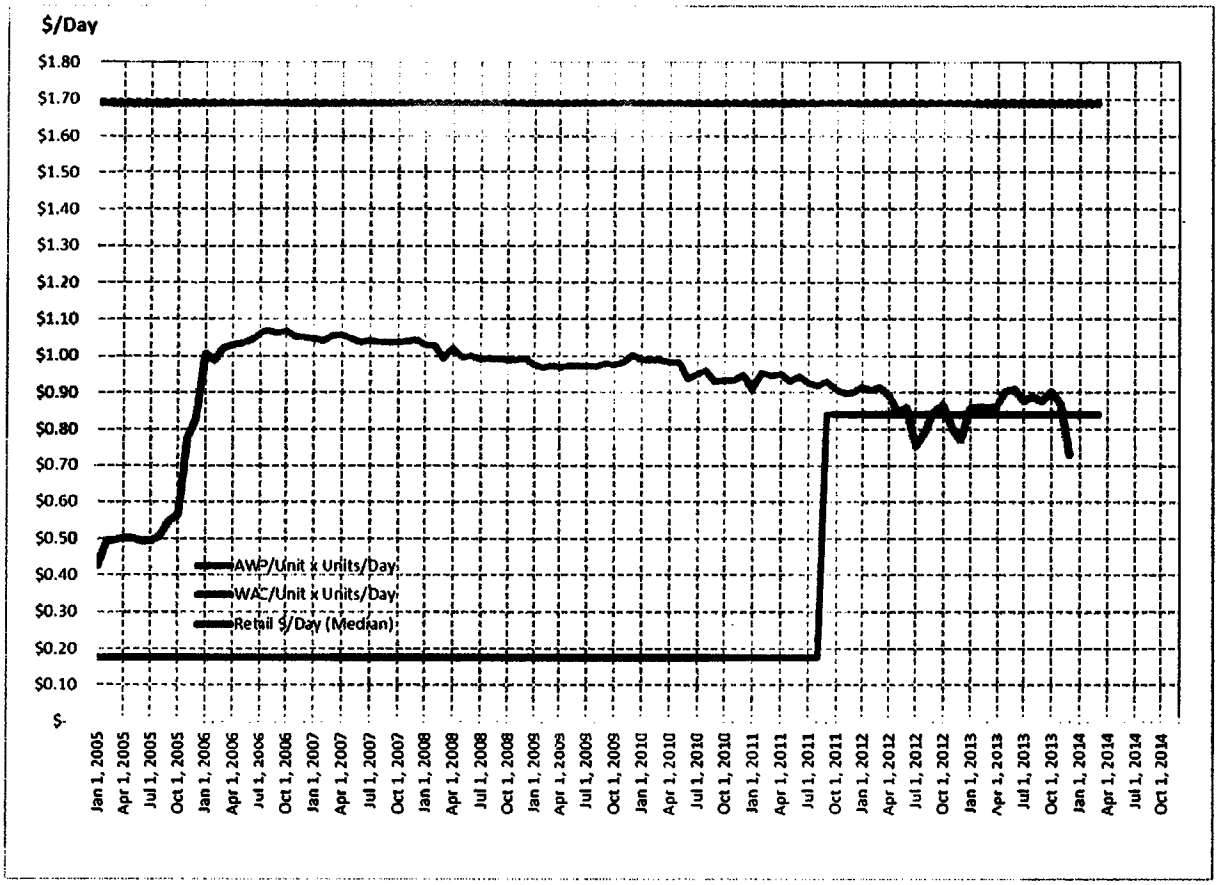


Figure 18. Meclizine HCl 25 mg Tablet (Par) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

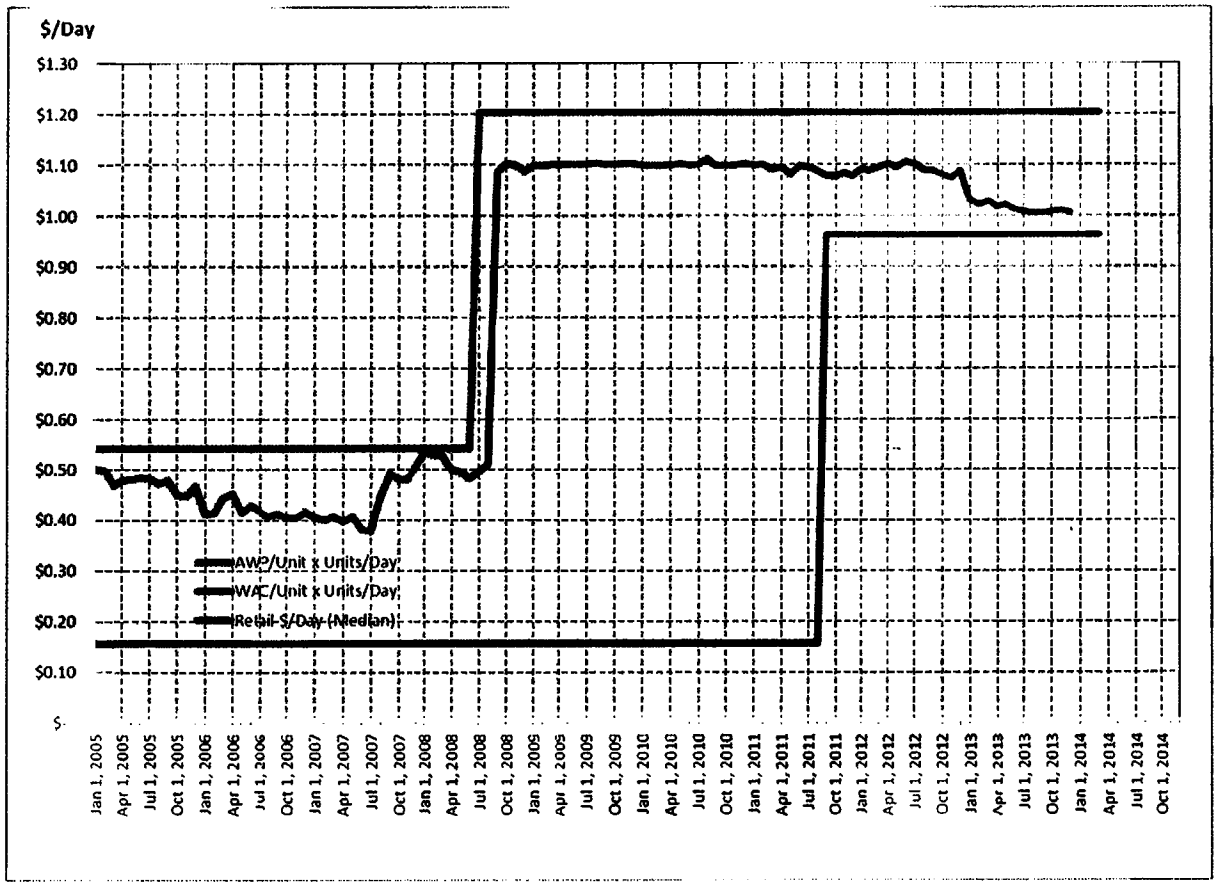


EXHIBIT "B"

Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs

November 2013

Table of Contents

Background

Section 1927(f) of the Social Security Act provides, in part, that CMS may contract with a vendor to conduct monthly surveys with respect to prices for covered outpatient drugs dispensed by retail community pharmacies. In addition, section 1927(i) also provides in part that CMS complete an annual report to Congress that includes ingredient costs paid for single source, multiple source, and non-prescription covered outpatient drugs.

Monthly surveys focus on the drug prices that retail community pharmacies pay to acquire drugs. Specifically, the vendor surveys these acquisition costs of covered outpatient drugs purchased by independent and chain retail community pharmacies.

State Medicaid agencies reimburse participating pharmacy providers for covered outpatient drugs that are prescribed and dispensed to Medicaid beneficiaries. The payment consists of two parts: 1) reimbursement for drug ingredient costs, and 2) reimbursement for the cost of dispensing. In general, federal regulations require that Medicaid programs reimburse for drug ingredient costs at no more than the agency's best estimate of the acquisition cost for a drug. As defined in federal regulations at § 42 CFR 447.502, estimated acquisition cost (EAC) is the state's best estimate of the prices generally and currently paid by providers for a drug marketed or sold by manufacturers or labelers in the package size of the drug most frequently purchased by providers.

Many Medicaid agencies currently utilize published drug pricing benchmarks to determine the EAC for drug ingredient costs. The Average Wholesale Price (AWP) was a primary drug pricing benchmark utilized in pharmaceutical reimbursement by state Medicaid agencies. However, this benchmark has been the subject of much scrutiny and litigation over concerns that many AWPs were artificially inflated. The effect of artificially inflated AWPs results in an overstatement of EACs and consequently the overpayment of the ingredient costs for drugs by state Medicaid agencies. Through numerous investigations, the Office of Inspector General found that AWP-based reimbursement was "fundamentally flawed" and caused Medicaid to pay too much for certain drugs.[1] Following the AWP litigation, a major publisher of pharmacy data discontinued its publication of AWP in September 2011. This heightened the need for an alternative data source for states to use when setting drug ingredient costs. Other published drug pricing benchmarks, such as Wholesale Acquisition Cost (WAC), Average Sales Price (ASP), and Direct Price (DP) are available for consideration, but each has limitations.

[1] Replacing Average Wholesale Price: Medicaid Drug Payment Policy. Office of Inspector General. July 2011. http://www.oig.hhs.gov/oei/reports/oei-03-11-00060.pdf

In late 2009, a working group within the National Association of State Medicaid Directors (NASMD) convened to discuss various alternatives to AWP. The working group authored a white paper in June 2010 entitled "Post AWP Pricing and Reimbursement" that evaluated and developed options for the replacement of AWP in Medicaid reimbursement methodologies. Among the recommendations presented in the white paper was the establishment of a single national pricing benchmark based on average drug acquisition costs. Such a benchmark would provide state Medicaid agencies with a better estimate of prices paid by pharmacies for drugs because it would be based upon actual drug purchases. This approach to drug ingredient price determination provides greater accuracy and transparency in how drug prices are established and is generally more resistant to manipulation. The NASMD requested that CMS coordinate, develop, and support this benchmark.

CMS contracted with Myers and Stauffer LC, a national certified public accounting firm, to conduct surveys of retail community pharmacy prices, including drug ingredient costs, and to develop the National Average Drug Acquisition Cost (NADAC) pricing benchmark. The NADAC survey process focuses on retail community pharmacy drug ingredient costs. The survey collects acquisition costs for covered outpatient drugs purchased by retail community pharmacies, which include invoice purchase prices from independent and chain retail community pharmacies.

Included in the Survey of Retail Prices, in addition to a survey of the cost pharmacies incur to purchase drugs, CMS collects information on consumer prices for the purchase of drugs. This survey focuses on the collection of retail community pharmacy prices charged to consumers and the calculation of consumer unit drug prices. These unit drug prices, which represent the prices charged to consumers are reported as the National Average Retail Price (NARP). The NARP is comprised of a statistically weighted average of three types of consumers: cash paying consumers, commercial third-party insurance consumers, and Medicaid consumers. Each consumer type will have unit prices identified by their 11-digit National Drug Code (NDC). The methodology for calculating the NARP is presented in a separate document.

Purpose

The purpose of this document is to describe and illustrate the methodology utilized to calculate the NADAC for Medicaid covered outpatient drugs.

The NADAC is designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs. States may want to consider the use of the NADAC. However, we note that a state must submit a state plan amendment in accordance with the state plan requirements if it decides to use NADACs as a basis for payment.

NADAC Reporting Level

The NADAC for prescription and over-the-counter covered outpatient drugs is reported at the 11-digit National Drug Code (NDC) level. The NADAC is calculated at the drug grouping, drug category, and pharmacy type level.

Drug grouping is primarily based on active ingredient(s), strength, dosage form, and route of administration. In most cases, NDCs for drugs that are pharmaceutically equivalent are assigned to the same drug group.

In some cases, additional parameters are included in defining a drug group. For example, package size is included as an additional delineation when there is a demonstrated variation in acquisition prices between package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing (e.g., topical creams and ointments). Please refer to the "NADAC Calculation" section for more details.

Drug category represents the classification of each NDC as one of the following: Single source ('S'), Innovator multiple source ('I'), or Non-innovator multiple source ('N'). In general, NDCs designated as 'S' and 'I' are considered brand drugs and NDCs designated as 'N' are considered generic drugs for purposes of calculating the NADAC. Drug category designations are listed in the "Classification for Rate Setting" field in the NADAC reference file. The Drug Category is obtained from the most recent CMS covered outpatient drug product file.

Drug category overrides indicate when the CMS covered outpatient drug product file drug category, 'S', 'I', and 'N' has not been applied. The override indicator is to alert states that this S/I/N categorization was not followed during the NADAC calculation for the applicable NDCs. In light of this, the process to override the drug category is necessary to align with reimbursement designations used by states for these drugs. States will not be required to match the NADAC designations or to reconcile previous reimbursement to match overrides.

When utilizing the NADAC for reimbursement, state Medicaid programs have the flexibility to apply their own brand or generic designations when determining reimbursement for these drugs. States must submit a state plan amendment in accordance with state plan requirements if they decide to use NADACs as a basis for payment.

For example, authorized generic drugs are listed in the CMS covered outpatient drug product file as 'I' drugs as they were approved under a New Drug Application (NDA).

For NADAC calculations, authorized generic drugs are identified as generic drugs since they are generally designated as generic by most state Medicaid programs for the purposes of reimbursement.

Another example is proprietary named drugs, approved under an Abbreviated New Drug Application (ANDA), and labeled 'N' in the CMS covered outpatient drug product file. For NADAC calculations, proprietary named drugs, approved under an ANDA are identified as brand drugs since they are generally marketed and priced as brand drugs. In this example, the NDC is identified with a 'B-ANDA' designation in the "Classification for Rate Setting" field of the NADAC reference file and, if available, both the brand and corresponding generic pricing are shown.

Pharmacy type is the classification of a pharmacy into categories. There is currently one type of pharmacy: retail community pharmacy as defined in section 1927(k) of the Social Security Act. For purposes of the NADAC, only chain and independent pharmacies have been surveyed.

Application of NADACs to Individual NDCs

The below example illustrates the application of NADACs to NDCs using the drug grouping, drug category and pharmacy type indicator. Only NDCs with the same drug grouping, drug category and pharmacy type indicator will share the same NADAC.

Example 1: Application of NADACs to Individual NDCs

Drug Grouping	NDC	Drug Category	Pharmacy Type Indicator	NADAC
Lipitor 10mg tablet	xxxxx-xxxx-xx	S/I	C/I	2.00000
atorvastatin 10mg tablet	xxxxx-xxxx-xx	N	C/I	1.00000
Lipitor 20mg tablet	xxxxx-xxxx-xx	S/I	C/I	4.00000
atorvastatin 20mg tablet	xxxxx-xxxx-xx	N	C/I	3.00000

Note: This example does not illustrate the contents of the NADAC file, show actual NADACs, or list all NDCs for these drug groupings.

Drug Grouping: All NDCs for Lipitor and atorvastatin 10mg tablets are classified into one drug group since they contain the same combination of active ingredient, strength,

dosage form, and route of administration. However, when a NADAC is calculated for the applicable NDCs in the drug group, these NDCs are further delineated by drug category and pharmacy type. Likewise, the NDCs for Lipitor and atorvastatin 20mg tablets would be classified together into a drug group separate from the 10mg version, due to the different strengths (10mg versus 20mg).

Please note that a drug group is comprised of pharmaceutically equivalent products at the active ingredient, strength, dosage form and route of administration level. Oral dosage forms of tablets and capsules will not be separated by package size. A NADAC may be calculated for package sizes within a drug group when the drug form is 'ml' or 'gram'.

Drug Category: The drug category differentiates the 'S/I' NDCs and the 'N' NDCs. Among NDCs with the same drug grouping, NDCs with a drug category of 'S/I' will receive the brand NADAC and NDCs with a drug category of 'N' will receive the generic NADAC. This is illustrated in the example for Lipitor 10mg tablets and atorvastatin 10mg tablets having the same drug grouping but different drug categories and therefore different NADACs.

Pharmacy Type Indicator: The pharmacy type indicator of C/I signifies that the NADAC was based on drug acquisition costs from chain and independent pharmacies.

Data Sources

Numerous data sources are relied upon in order to facilitate the collection, calculation, analysis and reporting of the NADAC. Those data sources include:

- Drug acquisition cost data collected through voluntary monthly surveys of retail community pharmacy entities (independent and chain pharmacies). .
- A national pharmacy file used to identify individual pharmacies.
- Drug identification and published pricing information obtained from CMS and verified that NDCs meet NADAC criteria.
- The most recently available covered outpatient drug product file from CMS's Medicaid website, Medicaid.gov, to use in NADAC criteria evaluation. In addition, interim updates, when available, are received from CMS for newly available covered outpatient drugs.
- The most recently available CMS list of labelers that are in the Medicaid Drug Rebate file (MDR) from CMS's Medicaid website, Medicaid.gov, to use in NADAC criteria evaluation. In addition, weekly updates, when available, are received from CMS for new rebating labelers.

Data Collection – Monthly Survey Process

On a monthly basis, Myers and Stauffer LC will collect acquisition cost data from a random sample of pharmacies selected from all 50 states and the District of Columbia. Pharmacy entities surveyed include independent and chain retail community pharmacies in the United States. A national pharmacy compendia file containing information on retail pharmacies throughout the country is used to determine the pool of pharmacies eligible for each survey.

Independent and Chain Pharmacies - A random sample of independent and chain retail community pharmacies is generated each month. The sample is drawn from the total population of such pharmacies. The composition of the survey sample closely aligns with the composition of the pharmacy population with regards to general pharmacy characteristics (i.e., independent, chain, rural, and urban).

Specialty Pharmacies - Specialty pharmacies are excluded from the surveys at this time. Specialty pharmacies are identified by their classification as primarily specialty pharmacies in the National Council for Prescription Drug Programs (NCPDP) database. Furthermore, the Utilization Review Accreditation Commission (URAC) specialty pharmacy certification list is also used as a supplement to identify additional specialty pharmacies for exclusion from the surveys.

Survey Process – Prior to the first of each month, survey letters are mailed to the physical location address of each selected pharmacy. The survey letter requests the voluntary submission of drug acquisition cost data from the pharmacy's previous month of drug purchases. Pharmacies are asked to submit the requested information within two (2) weeks. Upon request from a pharmacy, survey letters can also be sent by electronic mail to the pharmacy or, in the case of chain providers, a corporate contact. Reminders are sent 10 to 14 days following the initial letter.

Survey Request – Pharmacies are requested to voluntarily submit invoices on all covered outpatient drug purchases made from all wholesalers or manufacturers during the specified time period. Information requested through the survey consists of a minimum of the following:

- NDC
- Unit Price Paid
- Invoice Date
- Quantity Purchased

The data items listed above are the only information collected from submitted documents that is used in calculating the NADAC. Other information from the survey submissions is not used for calculating the NADAC.

The information collected through the survey is information that is already contained in documentation maintained by a pharmacy; therefore, it is readily available and requires minimal effort to locate, identify and submit. The time needed to respond to the survey request should take no more than 30 minutes of non-pharmacist staff time. Moreover, many pharmacy inventory systems have functionality that allows them to easily and quickly produce and send a report that includes the requested survey information. Another option available to pharmacies is to contact their wholesalers and request that they produce and send the requested survey information on the pharmacy's behalf. Survey data is accepted in hard copy and electronic formats.

Pharmacy invoices that reflect drugs purchased through the 340B program are requested to be excluded from survey submissions. If invoices with 340B pricing are submitted and able to be identified they are excluded from the NADAC calculation. When pricing varies from a range of expected values, further research is done to determine if the pricing reflects 340B pricing including contacting the provider to confirm the type of acquisition prices being submitted. For purposes of this survey, discounts or rebates that are not reflected on the invoice at the drug line item level are not factored into the NADAC calculation.

In addition to information on drug purchases, pharmacies are requested to send back the cover sheet that accompanied the survey letter. This cover sheet indicates the pharmacy's intent that its submitted information remain confidential. If the cover sheet or other documentation requesting confidentiality is not included in the pharmacy's submission, Myers and Stauffer LC will contact the pharmacy to confirm its intent regarding the confidentiality of the submitted data. Regardless, please note that CMS is the owner of submitted data and Myers and Stauffer LC is contractually prohibited from releasing this data to any other parties. Refer to Appendix 3 of this document for a sample of the survey letter and cover sheet.

Processing of Survey Data

Acquisition cost data submitted for the survey is accepted in many formats. Pharmacies or their wholesalers can submit their acquisition costs in electronic format via electronic mail delivery, send hard copy duplicates via postal mail, or transmit submissions via facsimile.

As survey responses are received, several tasks are performed to process the submissions. Submissions are entered in a receipt log to ensure that survey responses are tracked and counted. Whether a pharmacy has marked its submission as confidential is tracked. In cases where the pharmacy has not indicated that data provided are confidential, Myers and Stauffer LC will contact the pharmacy to clarify whether this omission was intentional. If the pharmacy chooses to indicate that its submission is confidential, a note is made in the receipt log.

Survey data is reviewed to ensure that costs entered into the database reflect the submitted data and that the NDCs are valid and active. Myers and Stauffer LC may contact pharmacies that submitted survey data to clarify questions about the submissions. Drug prices that are found to be equal to or greater than AWP are evaluated in accordance with the process described in the "Quality Assurance" section of this document and entered into the database only if they meet the criteria for inclusion in that section. Refer to the "Background" section of this document for further discussion on limitations with the AWP.

If required data (e.g. NDC information) is not submitted or does not pass one of the quality assurance checks (such as NDCs that do not match the NDC listed in the CMS Medicaid Drug Rebate file or acquisition cost outliers), the vendor deems the submission is to be excluded from consideration in the calculation of the NADAC. Universal Product Code (UPC) and Health Related Item (HRI) codes, to the extent that they can be, are converted to their corresponding 11-digit NDCs for purposes of the NADAC calculation.

Survey data received in electronic format is directly imported while data received in hard copy are manually entered into the database. Once the database is complete, quality assurance procedures are performed to ensure that data are accurately and completely entered. Such procedures include comparisons between the actual submitted documents and related database entries, and reconciliation between the number of data lines submitted electronically versus those entered into the database.

All submitted electronic and hard copy survey responses are stored in a secure and confidential manner. Hard copy files are stored in a locked environment until sent to CMS or destroyed upon CMS direction in accordance with federal records retention requirements. All information submitted is the property of CMS, and Myers and Stauffer LC is prohibited from utilizing this data for any purpose other than as directed by CMS.

National Average Drug Acquisition Cost (NADAC) Calculation

Prior to NADAC calculations, the data are grouped based on active ingredient(s), strength, dosage form, and route of administration. The data is also classified according to its drug category as either single source (S), innovator multiple source (I), or non-innovator multiple source (N).

In order to be included in the NADAC calculations, the data must satisfy the following criteria:

- Data must be from pharmacies surveyed in the month under review.
- Invoice dates must be from the month under review.
- Acquisition cost data must be for valid, active NDCs listed in published pricing compendia. Obsolete NDCs and CMS-terminated NDCs are excluded from NADAC calculations.
- Products must be on the latest CMS covered outpatient drug product file or a newly added drug determined by CMS to be a covered outpatient drug as defined by section 1927 of the Social Security Act.
- Products must not have a code that indicates the drug has been declared less than effective by the CMS Drug Product Efficacy Study and Implementation (DESI). Such drugs, identified as having a CMS DESI code of 5 or 6, are excluded. CMS DESI codes are obtained from the CMS covered outpatient drug product file.
- Only one cost observation (a price that appears on an invoice), for each pharmacy, for each NDC, is included in the NADAC calculation. If a pharmacy submits more than one cost observation for the same NDC during the month, the cost observation with the latest date of purchase is used. Use of acquisition cost for the latest date of purchase allows for drug price changes that occur during the month to be reflected in the costs that are used to calculate the NADAC. If a pharmacy submits more than one cost observation for the same NDC with the same purchase date, the lowest cost is used. The basis for the inclusion of the lower rate is that if a pharmacy makes multiple purchases of the same NDC on the same purchase date, then the pharmacy is able to acquire the drug at the lowest cost possible.

A minimum number of cost observations necessary to calculate a NADAC has not been established. The number of cost observations necessary to obtain estimates with reasonable precision depends on the overall variation of acquisition costs, with no less than five cost observations used for NADAC calculations where costs are closely aligned. A thorough review of each NADAC calculation is performed to ensure reliable rate calculations, appropriate removal of outlier costs, and other measures defined in the "Quality Assurance" section of this document.

The NADAC rate, defined by drug grouping, drug category, and pharmacy type is calculated as the average of the per unit cost observations. The NADAC is a simple average of the drug acquisition costs submitted by retail community pharmacies. NADACs are calculated as a single national average; regional price variations are not incorporated at this time as the relative impact on the NADAC calculation is minimal. Also, NADACs are not weighted based upon independent or chain pharmacy types as the relative impact of the differences in their respective acquisition costs are minimal.

The dispersion of drug prices is measured by the standard deviation. Cost observations greater than +/- two (2) standard deviations from the mean are removed as outliers. This approach eliminates values that are substantially inconsistent with the majority of observations, while retaining a large majority of cost observations used to calculate a mean. Other outlier removal processes have been examined by consulting statisticians. At this time, this approach is the most effective process for removing outliers.

Once outlier observations are removed, the average of the remaining per unit costs is calculated. A drug-by-drug review of the remaining cost observations is conducted by a review team comprised of pharmacists and analysts.

Separate NADACs are calculated for 'S/I' drugs and 'N' drugs. The NADAC for 'S' and 'I' products is referred to as brand drug NADACs. The NADAC for 'N' products is referred to as generic drug NADACs. Generally, there is one brand drug NADAC for 'S' and 'I' NDCs within a drug grouping. Likewise, one generic drug NADAC will apply to all 'N' NDCs within a drug grouping. This aligns with brand and generic reimbursement policies and requirements generally utilized by state Medicaid programs. For example, in accordance with their approved state plan, Medicaid programs may generally use a different reimbursement rate for brand drugs when a multiple source brand is preferred on the PDL or if the prescription is written as brand medically necessary.

Application of Drug Category Overrides

Since the primary purpose of the drug category field in the CMS covered outpatient drug product file is to support the Medicaid Drug Rebate Program (MDRP) for the calculation and determination of rebates due from manufacturers to state Medicaid programs, it is necessary to make some adjustments to the application of these values to assist in their use as a basis for payment. Cost data for single source ('S') and innovator multiple source ('I') products are separated from non-innovator multiple source ('N') products for NADAC calculations. The 'S', 'I', and 'N' designations are determined using the most current CMS covered outpatient drug product file. Processes to override the drug category to generally align with reimbursement designations used by states is described in further detail in the "NADAC Reporting Level" section of this document.

The following is an example of the use of the drug category and drug category overrides for NADAC purposes.

Example 2: Use of Drug Category Overrides for Application of NADACs to Individual NDCs

Drug Name (Labeler)	NDC	Drug Category	NADAC Per Unit	Note
Lipitor 10mg tablet (Manufacturer A)	xxxxx-xxxx-xx	S/I	2.00000	-
atorvastatin 10mg tablet (Manufacturer B)	xxxxx-xxxx-xx	N	1.00000	-
atorvastatin 10mg tablet (Manufacturer C)	xxxxx-xxxx-xx	N	1.00000	-
atorvastatin 10mg tablet (Manufacturer D)	xxxxx-xxxx-xx	S/I	1.00000	Overridden to a generic drug NADAC due to authorized generic status

Note: This example does not illustrate the contents of the NADAC file, show actual NADACs, or list all NDCs for this drug grouping.

This example illustrates the use of drug category overrides for the application of NADACs to NDCs.

In this example, Lipitor 10mg tablet is a brand drug and the NADAC that applies to this NDC within this drug grouping has a drug category of 'S/I'. Atorvastatin made by

manufacturers B and C are generic drugs, and the NADAC that applies to these NDCs within this drug grouping have a drug category of 'N.'

The NDC for atorvastatin made by Manufacturer D has a drug category of 'S/I' on the covered outpatient drug file. However, it is an authorized generic drug so state Medicaid programs may consider this drug to be a generic drug and in such situations, the drug category is overridden.

Application of Differential NADACs Based on Package Size

There are some situations where exceptions to NADAC drug grouping are applied to ensure appropriate drug grouping. While most NADAC drug groupings will consist of all package sizes available, a separate NADAC may be calculated for package sizes within a drug grouping when the drug form is 'ml' or 'gram' and when there is a demonstrated variation in acquisition costs between package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing (e.g., topical creams and ointments). Drug forms with kits will also be evaluated for pricing per package size. These situations require the use of differential NADAC drug groupings that vary by package size. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / package size combinations.

Application of Differential NADACs Based on Drug Class

Another situation of exceptions to the typical NADAC drug grouping process is calculating separate NADACs based upon a drug's class. Drug class is based on whether a prescription is required for dispensing a drug product. If a prescription is required, the NDC is referred to as 'legend.' If a prescription is not required, the NDC is referred to as 'over-the-counter,' or 'OTC.' The OTC field on the NADAC file will indicate whether the NDC is considered legend or OTC.

Different NADAC groups are assigned in cases where NDCs within a NADAC drug grouping share identical active ingredients, strength, dosage form, and route of administration but differ by drug class. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / drug class combinations. In other words, NADACs for legend drugs are calculated only from costs for legend drug NDCs. Also, over-the-counter (OTC) drugs are calculated only from costs for OTC NDCs. As with all Medicaid covered outpatient drugs, a prescription is required.

Application of Differential NADACs Based on Therapeutic Equivalency

Therapeutic equivalency is the equivalency rating assigned by the FDA as reported in the Orange Book. The majority of NADAC drug groupings will consist of NDCs that share the same therapeutic equivalency. For a small number of NADAC drug groupings where NDCs share identical active ingredients, strength, dosage form, and route of administration but differ by therapeutic equivalency, there is a need to subdivide the group and calculate separate NADACs per therapeutic equivalency code. These NADACs are calculated for unique drug grouping / drug category / pharmacy type / therapeutic equivalency combinations. In other words, NADACs for drugs with a specific therapeutic equivalency code are calculated only from costs for NDCs with that specific therapeutic equivalency code.

Application of Differential NADACs Based on Multiple Brand Manufacturers Within the Same NADAC Grouping

Brand drug NADAC will generally be based upon the products from a single manufacturer that is identified as the innovator of the drug grouping. There are situations where products from more than one manufacturer within a drug grouping are classified as brand drugs by state Medicaid programs and separate NADACs are calculated per manufacturer product within the same drug grouping.

Statistical Validity

Validity means that that the sample mean is an accurate estimate of the true mean and the sample mean is estimated precisely. Simple random sampling helps to ensure accuracy as the sample reflects the characteristics of the population. Precision depends upon the characteristics of the sample. In particular, as the observations in the population become more concentrated around a single value, the sample mean becomes more precise.

Brand drug NADACs exhibit a high level of precision, demonstrated by low margins of error. For brand drugs, 99.3% of NADACs have a margin of error of less than 5% of the mean unit cost at a confidence interval of 95%. In other words, 99.3% of the NADACs for brand drugs are within 5% of the true average drug cost 95 out of 100 times. The average margin of error as a percent of the mean unit cost is very low at 0.5%, at a confidence level of 95%. For context, the average per unit NADAC for brand drugs is approximately $5.00

As with brand drug NADACs, calculations for generic drug NADACs result in high levels of precision with low margins of error. For generic drugs, 100% of NADACs have a

margin of error of less than 10% of the mean unit cost at a confidence interval of 95%. In other words, 100% of the NADACs for generic drugs are within 10% of the true average drug cost 95 out of 100 times. The average margin of error as a percent of the mean unit cost is very low at 2.4%, at a confidence level of 95%. For context, the average per unit NADAC for generic drugs is approximately $0.28000.

NADAC Updates

NADAC file updates occur on a weekly and monthly schedule.

Non-innovator multiple source drugs (Generic drugs)

After an initial NADAC has been determined using the results of the monthly pharmacy acquisition cost surveys, it is reviewed for updates on both a weekly and monthly schedule.

On a weekly basis, the NADACs for generic drugs are reviewed and adjusted as necessary based on research initiated by pharmacy inquiries into the NADAC Help Desk. If research, such as evaluating marketplace availability and contacting other pharmacies, substantiates that a change in price for a generic drug has occurred, a revised NADAC is calculated and included in the next weekly NADAC reference file update. Refer to the "Help Desk Support Functions" section of this document for further details.

Provider inquiries regarding the NADAC will be investigated and evaluated based upon invoice data collected from the pharmacy initiating the review, additional pharmacies contacted by the help desk, and other market factors, such as compendia price changes. NADACs will be adjusted when drug pricing changes have been substantiated and those adjustments will be reflected in the NADAC rate updates published on a weekly basis.

In addition, new drugs as identified by CMS that meet the NADAC criteria are added.

On a monthly basis, existing NADACs for generic drugs are replaced with updated NADACs using the results of the ongoing monthly pharmacy acquisition cost surveys. New drugs as identified by CMS that meet the NADAC criteria are also added during the monthly update.

Some existing NADACs may not be updated due to limited subsequent survey data. In these cases, the existing NADAC for the generic drug will remain on the NADAC file until the sooner of 1) the first month for which a NADAC can be calculated, or 2) twelve months. If an updated NADAC cannot be calculated with survey data or updated based on Help Desk review after twelve consecutive months, the NADAC is removed from the NADAC reference file. Once a NADAC can be calculated for a previously removed drug grouping, the NADAC will again appear on the reference file.

Single source or Innovator multiple source drugs (Brand drugs)

Published pricing compendia pricing changes associated with brand drugs are considered prior to the publication of updated NADACs that are based on monthly surveys. Drug costs used for determining the brand drugs' NADAC are adjusted to reflect the relative change in published drug prices, as described below. This ensures that brand drug NADACs are reflective of current drug prices at the time of publication. After a NADAC has been determined using the results of the monthly pharmacy acquisition cost surveys, it is further reviewed for updates on a weekly schedule.

On a weekly basis, the NADACs for brand drugs are reviewed and adjusted as necessary based on changes in published prices. Changes in published prices are measured as the relative percentage difference between the new published price and the previous published price. Therefore, if the published price for a drug increases by 5%, then the NADAC for that drug is also increased by 5%. The pricing change is validated with survey data obtained from the next monthly survey. The relationship between changes in published brand drug prices and changes in actual brand drug prices obtained from surveys are tracked and monitored to ensure that a consistent correlation continues to exist.

Additionally, Myers and Stauffer LC operates a Help Desk to respond to inquiries related to drug price changes that are not reflected on the current NADAC reference file. NADACs are reviewed and adjusted based on research initiated in response to pharmacy inquiries made to the NADAC Help Desk. If research, such as evaluating marketplace availability and contacting other pharmacies, substantiates that a change in price for a generic drug has occurred, a revised NADAC is calculated and included in the next weekly NADAC reference file update. Refer to the "Help Desk Support Functions" section of this document for further details.

On a monthly basis, existing NADACs for brand drugs are evaluated and then updated based on new survey data. For consistency and smoothing purposes, the results of each subsequent monthly pharmacy acquisition cost survey for brand products are compared to the existing brand NADAC to evaluate whether a change is warranted. Historic month-over-month published pricing changes were evaluated to determine trends in pricing. A 2% pricing change variance threshold for brand drug NADACs was established after extensive analysis of published pricing changes. Published pricing changes were very rarely less than 2%. Therefore, changes of less than 2% from the previous month's brand NADAC will not warrant a change in the published NADAC. Since manufacturer published price changes are already being accounted for through the regular weekly processes, small pricing variations observed from month-to-month

are likely reflective of fluctuations due to the composition of responding pharmacies and not related to marketplace changes in the price of the drug. Utilizing this threshold in the evaluation of brand drug NADACs will avoid implementing NADAC adjustments that are not based on changes in marketplace prices.

Conversely, if the 2% variance threshold is exceeded, the current brand drug NADAC is replaced with the new brand drug NADAC based on the latest monthly survey findings. If the threshold is not exceeded, the current brand drug NADAC will remain on the NADAC file with the current Effective Date. Refer to the "Effective Date Assignment" section for details on effective dates.

NADACs for generic drugs do not have thresholds established since prices tend to be more volatile. Due to this volatility in pricing, a smoothing process would only serve to dampen the effects of true changes in market prices. Utilizing changes in published pricing for generic drug NADACs is also not practical since the relationship between reported prices and actual prices do not demonstrate a level of consistency for generic drugs as it does for brand drugs. In other words, published pricing changes for generic drugs has not been shown to represent actual pricing changes. Therefore, the calculated monthly NADACs for generic drugs are utilized without any smoothing processes.

Some existing NADACs may not be updated due to limited subsequent monthly survey data. In these cases, the existing NADAC for brand drugs will remain on the NADAC file until the sooner of 1) the first month for which a NADAC can be calculated, or 2) twelve months. If an updated NADAC cannot be calculated with survey data, or updated due to a change in published drug pricing or Help Desk review based on a pharmacy inquiry after twelve consecutive months, the NADAC is removed from the NADAC reference file. Once a NADAC can be calculated for a previously removed drug grouping, the NADAC will again appear on the reference file.

Addition of NADACs for new drugs not listed on current quarterly CMS covered outpatient drug product file

The CMS covered outpatient drug product file available on Medicaid.gov is updated on a quarterly basis. There may be instances when drugs that are new to the pharmacy marketplace are not listed until the next quarterly covered outpatient drug product file is published. The lag between the availability of the new drug product in the marketplace and its inclusion on the covered outpatient drug product file could potentially delay addition of new drugs to the NADAC file. To address these instances, Myers and Stauffer LC receive updates from CMS with regards to new drug products. The drug

category for the new drug is assigned through the drug category review process discussed in the "NADAC Calculation" section. When acquisition cost data is available for these new drugs, a NADAC is calculated and added to the NADAC reference file.

Deliverables

The NADAC reference file is publically available on CMS' Medicaid website, Medicaid.gov. The most current reference file is posted, and contains all NADACs and associated information. We expect that each file will contain NADACs for approximately 20,000 to 25,000 NDCs.

NADAC Reference File Format and Layout

The NADAC reference file is published as an Excel file. The file is sorted by NDC Description in alphabetical order and contains the following fields:

- NDC Description - Identifies the drug name, strength, and dosage form of the drug product.
- NDC – The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.
- NADAC Per Unit – The National Average Drug Acquisition Cost per unit.
- Effective Date – The effective date of the NADAC Per Unit cost.
- Pricing Unit – Indicates the pricing unit for the associated NDC ('ML', 'GM' or 'EA').
- Pharmacy Type Indicator – The source of pharmacy survey data used to calculate the NADAC. 'C/I' indicates data was collected from surveys of Chain/Independent pharmacies. Other pharmacy type indicators are not used at this time.
- OTC – Indicates whether or not the NDC is for an over-the-counter (OTC) product ('Y' or 'N').
- Explanation Code – Codes that pertain to how the NADAC was calculated. These codes are identified in an accompanying NADAC Data Field Definitions document that is posted on Medicaid.gov. Refer to Appendix 2 for further information.
- Classification for Rate Setting – Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. NDCs that were considered brand and are approved by the FDA under an Abbreviated New

Drug Application (ANDA) are designated with 'B-ANDA.' Please see more information on 'B-ANDA in the "NADAC Reporting Level" section of this document.

- Corresponding Generic Drug NADAC Per Unit *and* Corresponding Generic Drug NADAC Effective Date are presented in further detail later in this section.

Appendix 1 contains an example of the NADAC reference file.

NADAC Reference File Publication

The NADAC reference file is posted weekly on Medicaid.gov. The file contains all of the NDCs that have an assigned NADAC. Each NADAC reference file update contains a full listing of covered outpatient drug products' NDCs with assigned NADACs; therefore, this is a full reference file replacement each week. The header of the NADAC reference file indicates whether the NADAC updates reflect the results of the monthly acquisition cost survey or account for the weekly NADAC update processes described in the "NADAC Updates" section. The header will display

<Monthly/Weekly> NADAC Reference File as of <date>

Additional details regarding the reason for specific NADAC pricing changes is available in the NADAC Week-to-Week Comparison File, presented in further detail later in this section.

Once a NADAC is calculated for a drug grouping, the NADAC is only applied to covered outpatient drug NDCs within that group. NADACs are applied to the entire grouping regardless of whether or not costs were collected for a specific NDC within the drug group, however they will not be published for NDCs that are not CMS covered outpatient drugs.

NDCs with CMS Termination Dates that are before the posting date are excluded from the reference file. The updated NADAC reference file will replace the existing reference file available through the Medicaid.gov website. Changes to the NADAC reference file are identified through the Explanation Code field.

In addition to the NADAC reference file, an accompanying NADAC Data Field Definitions document is published to assist in the interpretation of the NADAC reference file. Information in this document includes the field names, field descriptions, and explanation codes.

Effective Date Assignment

The Effective Date associated with a NADAC will depend on whether the NADAC was updated.

- For NADACs that do not change from the previous reference file, the NADAC and Effective Date will carry forward to the new reference file.
- For NADACs that are added or changed from the previous reference file, a new Effective Date is assigned to the NADAC. This Effective Date is the date on which the NADAC becomes effective.

NADACs are posted two months after the surveyed pharmacy invoices are collected and utilized to calculate prices, as illustrated below.

Description	Month 1	Month 2
Date of Drug Purchases for Acquisition Costs	November 1 – November 30	December 1 – December 31
Month of Survey Collection, Processing and NADAC Calculations	December	January
Month of NADAC Reference File Publication	January	February

Please refer to the "NADAC Updates" section for more detail regarding how drug acquisition costs are updated prior to NADAC reference file publication.

Brand and Generic Drug NADACs for Multiple Source Brand Drug NDCs

In cases where a multiple source brand drug NDC and its corresponding generic drug counterpart both have assigned NADACs, the NADAC reference file will list the NADAC for the corresponding generic drug on the same record line as the multiple source brand

NDC. The effective date associated with the corresponding generic drug NADACs will also be shown on the same record line.

The NADAC reference file contains two columns where the corresponding generic drug NADAC information is contained. These columns are:

- Corresponding Generic Drug NADAC Per Unit – The NADAC for the corresponding generic drug.
- Corresponding Generic Drug NADAC Effective Date – The effective date of when the corresponding generic drug NADAC is assigned to a multiple source brand drug NDC. This date may not correspond to the NADAC effective date for the generic drug due to the method by which the corresponding generic drug NADAC effective date is assigned.

  The corresponding generic drug NADAC effective date is the latter of the following dates: a) date of the NADAC reference file upon which the corresponding generic drug NADAC first appears, b) the current corresponding generic drug NADAC effective date plus one day - one day is added to the previous date so that there are no overlapping rate segments, or c) the NADAC Effective Date for the generic drug group. This date assignment process is necessary to update the corresponding generic drug NADACs.

The corresponding generic drug NADAC columns will not be populated when 1) the NDC is not a multiple source brand drug, or 2) there is no NADAC for the corresponding generic drug.

NADAC Week-to-Week Comparison File

A separate file is published on the CMS Medicaid website, Medicaid.gov, that compares the most current NADAC reference file with the immediately preceding NADAC reference file. This comparison file is updated and published on a weekly basis.

The comparison will only consist of NDCs whose NADACs have changed since the previous NADAC reference file. The file will *not* be inclusive of all NDCs in the NADAC reference file. New NDCs or terminated NDCs are not included in this file. NDCs whose NADACs have not changed since the previous NADAC reference file will not be included in this file.

The file is sorted by NDC Description and will contain the following fields:

- NDC Description – Identifies the drug name, strength and dosage form of the drug product.
- NDC – The National Drug Code (NDC) is the numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.
- Old NADAC Per Unit – The National Average Drug Acquisition Cost per unit from the previous NADAC Reference File.
- New NADAC Per Unit – The National Average Drug Acquisition Cost per unit from the current NADAC Reference File.
- Classification for Rate Setting – Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA').
- Percent Change – The difference between the New NADAC Per Unit and the Old NADAC Per Unit, divided by the Old NADAC Per Unit.
- Primary Reason – Describes the primary reason for the NADAC Per Unit change, see explanation below for each reason:
    - Survey Rate: The NADAC Per Unit has been updated using information from the most recently completed pharmacy survey.
    - WAC Adjustment: The NADAC Per Unit has been updated to reflect changes in published pricing.
    - Help Desk Adjustment: The NADAC Per Unit has been updated as a result of an inquiry to the help desk.
    - Brand Generic Change: The NADAC Per Unit has been updated as a result of a change in the Classification for Rate Setting.

- Rate Group Change: The NADAC Per Unit has been updated due to placement into a new NADAC drug grouping because of a change in NDC attributes.

In addition to the NADAC Week-to-Week Comparison File, an accompanying NADAC Week-to-Week Comparison File Field Definitions document is published to assist in the interpretation of the file. Information in this document includes field names, field descriptions, and primary reasons.

Appendix 5 contains an example of the NADAC Week-to-Week Comparison File. Appendix 6 contains the NADAC Week-to-Week Comparison File data field definitions.

Quality Assurance

Myers and Stauffer LC fully incorporates quality assurance procedures to ensure that acquisition cost submissions are reasonable (as discussed below), are associated with valid, active NDCs, and calculations are performed in accordance with the methodology outlined in this document.

Prior to initiation of NADAC calculations, data is reviewed to ensure that costs entered into the database reflect the submitted data and that the NDCs are valid and active. Quality assurance checks are performed to ensure that acquisition costs are being reported and not being substituted with commercial pricing benchmarks such as AWP. For an entire submission from one pharmacy, the percentage of costs reported that are equal to or greater than AWP is calculated. If costs equal to or above AWP meet an established threshold in the aggregate, further investigation is initiated to ensure that actual cost data is submitted.

As part of this investigation process, individual pharmacies are contacted if there are questions with the pharmacy's acquisition cost submissions. As described earlier in the "NADAC Calculation" section, price outliers are removed through two processes. The first process removes all cost observations that are not within two (2) standard deviations from the mean acquisition cost for the drug grouping. This approach eliminates values that are substantially inconsistent with the majority of observations, while retaining a large majority of values used to calculate a mean.

The second process is a manual review of the NADAC calculations. A drug-by-drug review is conducted by a review team comprised of pharmacists and analysts to ensure that reliable NADAC calculations have been performed. These reviews consist of measures to determine the reliability of the NADACs. The array of invoice costs collected are carefully analyzed to determine if factors such as price increases or drug shortages during the invoice collection period may have adversely impacted the NADAC calculation. Obvious outliers, data entry/data import errors and package size discrepancies are identified and addressed. NADAC files are reviewed weekly and monthly to ensure consistency of drug groups, drug categories, and NDC counts. Additionally, large increases and decreases in NADACs prompt further research to confirm drug price changes.

These quality assurance measures prevent outlier acquisition costs from inappropriately impacting the NADAC calculation, distinguish potential inconsistencies in data, proactively identify changes that require further investigation, and ensure reliable NADAC calculations. Myers and Stauffer LC also performs an ongoing quality review of

calculations and procedures for the acquisition cost survey and NADAC reference file publication in order to continue to refine these processes. Examples of quality assurance analyses used for this type of review include monitoring price change trends compared to published price references and comparison of acquisition costs across various pharmacy characteristics, such as chain or independent pharmacies

Help Desk Support Functions

Myers and Stauffer LC supports a NADAC Help Desk, which is staffed with certified pharmacy technicians, trained analysts, and pharmacists. This Help Desk will assist pharmacies and state Medicaid agencies with the following types of issues only.

- Survey Support - Pharmacies are able to contact Myers and Stauffer LC with questions related to the survey, survey process, options for responding to the survey, what information to submit, or other related questions.
- Drug Price Changes – Pharmacies are able to provide notification of recent drug price changes that are not reflected in posted NADACs to the Help Desk. Help Desk staff may request additional information to assist in the research of these changes, such as invoices or screen shots of drug ordering systems reflecting current acquisition costs.

The Help Desk will receive and address each inquiry. Research will be performed to validate claims of drug pricing changes. Such research will include comparison to costs collected through the survey, confirmation of drug or material shortages, and confirmation of drug price changes with other pharmacies. Pharmacies will be informed that changes made to the NADAC as a result of the inquiry will be addressed in future published reference files. Providers can contact the Help Desk to receive an update on the status of their question if they are unclear of whether a NADAC was updated.

The Help Desk will not address pharmacy inquiries into specific State or claim reimbursement related questions or concerns.

The NADAC Help Desk can be contacted through the following means.

Toll-free phone: (855) 457-5264
Electronic mail: info@mslcrps.com
Facsimile: (317) 815-5478

Glossary

Term	Definition
Active Ingredient(s)	The active ingredient(s) represents the text description of the generic name of the drug product for the NDC.
Classification for Rate Setting	Indicates whether the NDC was brand ('B') or generic ('G') for the NADAC rate calculation process. NDCs that were reported brand and are approved by FDA under an Abbreviated New Drug Application (ANDA) are designated by 'B-ANDA.'
CMS Termination Date	Date the drug was withdrawn from market or the drug's last lot expiration date.
CMS Drug Category	'S/I' drug or 'N' drug, as determined through the 'Single-source', 'Innovator Multiple Source', and 'Non-innovator Multiple Source' drug category designations listed on the most current CMS outpatient covered drug product file.
CMS DESI Code	Drug Product Efficacy Study and Implementation (DESI) codes obtained from the CMS covered outpatient drug product file. Products must not have a code that indicates that it is less than effective. Such drugs, identified by having a CMS DESI code of 5 or 6, are excluded from NADAC calculations.
Corresponding Generic Drug NADAC Per Unit	The NADAC for the corresponding generic drug that is assigned to a multiple source brand drug NDC.
Corresponding Generic Drug NADAC Effective Date	The date when the corresponding generic drug NADAC is assigned to a multiple source brand drug NDC.

Term	Definition
Drug Grouping	The drug grouping is based on active ingredient, strength, dosage form, and route of administration for a formulation. In some cases, the drug grouping is further differentiated by package size. This additional delineation occurs when there is a demonstrated variation of acquisition cost among package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing.
Effective Date	The effective date of the NADAC Per Unit cost.
Explanation Code	Codes that pertain to how the NADAC was calculated. These codes are identified in an accompanying NADAC Data Field Definitions document that is posted on Medicaid.gov. Refer to Appendix 2 for further information.
NADAC	The National Average Drug Acquisition Cost (NADAC). Represents a national pricing benchmark that is reflective of actual invoice costs that pharmacies pay to acquire prescription and over-the-counter drugs. It is based upon invoice cost data collected from retail community pharmacies and reflects actual drug purchases.
NDC	The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.
NDC Description	Identifies the drug name, strength, and dosage form of the drug product.

Term	Definition
Obsolete Date	The estimated date reported by the manufacturer, that indicates the NDC is to be discontinued, no longer marketed, no longer produced, no longer distributed, or otherwise made unavailable to the marketplace. This date is obtained from drug information compendia.
Outlier	Drug cost observations that exhibit a deviation from other known cost observations for similar drugs. The two standard deviation approach combined with a manual review is the most effective process for removing outliers.
Pharmacy Type	A category of pharmacies. Entities such as chain and independent pharmacies (C/I), as determined through self-reported pharmacy identification, or other supplemental resources. This information is obtained from a national pharmacy compendia file. A chain pharmacy is defined as a pharmacy that belongs to a group of four or more pharmacies that are all under the same ownership and all have the same name. An independent pharmacy is defined as a pharmacy that is not owned or operated by a chain. Franchise pharmacies are classified as independent pharmacies.
Pricing Unit	Indicates the pricing unit for the associated NDC (e.g., 'ML', 'GM', or 'EA').
Specialty Pharmacy	Pharmacies that dispense specialty drugs, as identified by the classification of their pharmacies as primarily specialty pharmacies in the National Council for Prescription Drug Programs (NCPDP) database. In addition, URAC specialty pharmacy certification is used as a supplement to identify specialty pharmacies.

Appendix

1) Sample NADAC Reference File
2) NADAC Data Fields Definitions
3) Survey Letter and Cover Sheet
4) Paperwork Reduction Act Statement
5) Sample NADAC Week-to-Week Comparison File
6) NADAC Week-to-Week Comparison File Data Fields Definitions

APPENDIX 1: Sample NADAC Reference File, with a deliverable date of 2/15/2013

NDC Description	NDC	NADAC Per Unit	Effective Date	Pricing Unit	Pharmacy Type Indicator	OTC	Explanation Code[1]	Classification for Rate Setting	Corresponding Generic Drug NADAC Per Unit	Corresponding Generic Drug NADAC Per Unit
Drug A 5mg Tab	xxxxx-xxxx-xx	0.12345	1/1/2013	Tablet	C/I	N	1,6	G	-	-
Drug B 5mg Tab	xxxxx-xxxx-xx	6.54321	2/1/2013	Tablet	C/I	N	1	B	0.12345	2/15/2013
Drug C 15mg Tab	xxxxx-xxxx-xx	12.34567	2/1/2013	Tablet	C/I	N	1	B-ANDA	0.98765	2/1/2013

[1]NADAC Attribute - 1 identifies that the posted NADAC reflects the average cost from submitted invoice costs only. NADAC Attribute - 6 identifies that the drug category on the CMS covered outpatient drug product file was not applied (overridden).

In the example above, Drug B is a multisource brand drug and Drug A is its corresponding generic drug. Please refer to the discussion on *Brand and Generic Drug NADACs for Multiple Source Brand Drug NDCs* within the *Deliverables* section of this document for further explanation of the corresponding generic drug NADAC columns.

Drug C is an example of a drug that is classified as a brand drug for purposes of Medicaid payment and is approved by FDA under an Abbreviated New Drug Application (ANDA).

APPENDIX 2: NADAC Data Field Definitions

NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC) DATA FIELD DEFINITIONS

National Drug Code (NDC) Description:
Identifies the drug name, strength, and dosage form of the drug product.

NDC:
The National Drug Code (NDC) is a numerical code maintained by the FDA that includes the labeler code, product code, and package code. The NDC is an 11-digit code.

NADAC Per Unit:
The National Average Drug Acquisition Cost per unit.

Effective Date:
The effective date of the NADAC Per Unit cost.

Pricing Unit:
Indicates the pricing unit for the associated NDC ('ML', 'GM' or 'EA').

Pharmacy Type Indicator:
The source of pharmacy survey data used to calculate the NADAC. 'C/I' indicates data was collected from surveys of Chain/Independent pharmacies. Other pharmacy type indicators are not used at this time.

OTC:
Indicates whether or not the NDC is for an over-the-counter (OTC) product ('Y' or 'N').

Explanation Code:
Codes that pertain to how the NADAC was calculated; see explanation codes below:

- Code 1: The NADAC was calculated using information from the most recently completed pharmacy survey.
- Code 2: The average acquisition cost of the most recent survey was within ± 2% of the current NADAC; therefore, the NADAC was carried forward from the previous file.
- Code 3: The NADAC based on survey data has been adjusted to reflect changes in published pricing, or as a result of an inquiry to the help desk.
- Code 4: The NADAC was carried forward from the previous file.
- Code 5: The NADAC was calculated based on package size.

- Code 6: The CMS Covered Outpatient File drug category type of 'S/I/N' (Single Source/Innovator/Non-Innovator) has not been applied. Most 'S/I' drugs with the same strength, dosage form and route of administration were grouped together for the purpose of the NADAC calculation and 'N' drugs were also grouped together. In some cases, however, in calculating a NADAC, the CMS 'S/I/N' designation was not applied when the state Medicaid brand or generic payment practices for these drugs generally differed from the CMS Covered Outpatient File designation.

  For example, authorized generic drugs are listed in the CMS covered outpatient drug file as 'I' drugs for the purpose of rebates as they were approved under a New Drug Application (NDA). However, they are grouped as 'N' for the NADAC calculation since they are generally designated as generic by most state Medicaid programs for the purposes of reimbursement. Another example of this occurrence is when proprietary named drugs, approved under an Abbreviated New Drug Application (ANDA) are in the CMS Covered Outpatient Drug file as 'N' for the purpose of rebates. However, they are grouped as 'S/I' for the NADAC calculation since they are generally reimbursed as brand drugs by state Medicaid programs.

- Codes 7 through 10: Reserved for future use.

Classification for Rate Setting:
Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA').

Corresponding Generic Drug NADAC Per Unit:
The NADAC for the corresponding generic drug.

Corresponding Generic Drug Effective Date:
The effective date of when the Corresponding Generic Drug NADAC Per Unit is assigned to a multiple source brand drug NDC. This date may not correspond to the NADAC effective date for the generic drug due to the method by which the corresponding generic drug NADAC effective date is assigned.

The corresponding generic drug NADAC effective date is the latter of the following dates: a) date of the NADAC reference file upon which the corresponding generic drug NADAC first appears, b) the current corresponding generic drug NADAC effective date plus one day – one day is added to the previous date so that there are no overlapping rate segments, or c) the NADAC Effective Date for the generic drug group. This data assignment process is necessary to eliminate the potential for applying corresponding generic drug NADACs to past claims.

APPENDIX 3: Survey Letter

Center for Medicaid and CHIP Services

March 1, 2013

Dear Pharmacy Owner / Manager:

As you are aware, changes in the availability of drug pricing benchmarks necessitate that many State Medicaid programs evaluate alternative pricing methods for use in reimbursing pharmacies for drugs that they dispense. Because of these changes, we have the unique opportunity to work together to recognize the contributions pharmacists make to the health of Medicaid recipients through the realignment of drug ingredient reimbursement for estimating pharmacy's acquisition costs, and the provision of reasonable Medicaid dispensing fees that consider professional services performed by pharmacists.

The Centers for Medicare and Medicaid Services (CMS) is working with State Medicaid programs, with input from national pharmacy associations and many other stakeholders, regarding the design and development of a National Average Drug Acquisition Cost (NADAC) reference file. We expect that the NADAC reference file will represent a new pricing benchmark based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchmark will be based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey will be conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date.

CMS envisions that the NADAC reference file will provide State Medicaid agencies with an additional pricing reference which they can use to evaluate their current drug reimbursement methodologies. If a Medicaid program chooses to utilize the NADAC reference file for drug ingredient reimbursement, we expect that States will simultaneously evaluate their Medicaid dispensing fee.

One of the primary goals of this program is to create and maintain an up-to-date NADAC reference list for Medicaid covered outpatient drugs reflecting the average price paid for drugs by entities (e.g., independent pharmacies and chain pharmacies in the United States). The drug acquisition cost survey process has been designed to minimize the administrative burdens on pharmacies that participate and to streamline the process of obtaining drug cost data from pharmacies.

CMS has contracted with Myers and Stauffer LC, a national certified public accounting firm that provides professional accounting, consulting, data management and analysis services to government-sponsored healthcare programs. Myers and Stauffer has extensive experience working with State Medicaid pharmacy programs and collecting acquisition costs directly from pharmacies. Under this CMS contract, Myers and Stauffer has developed a methodology for collecting drug acquisition costs and calculating the NADAC reference file prices for covered outpatient drugs.

A meeting with stakeholders was held on August 4, 2011 at the CMS offices in Baltimore, during which the proposed methodology for the NADAC was presented. Since that meeting, further stakeholder input has been received and considered in the final design and development of the drug acquisition cost survey and NADAC reference file initiative. Additional information and routine updates will be available from the http://www.Medicaid.gov website.

Over →
OMB Control #0938-1041

Your pharmacy has been randomly selected to participate in this month's survey. We are requesting that you provide a copy of the selected purchase invoices for drugs purchased by your pharmacy. The attached survey instructions prepared by Myers and Stauffer outline the survey process for submitting one (1) month's worth of drug invoices by fax, mail, or electronic submission. Since 2,000 to 2,500 pharmacies nationwide are randomly selected to participate in the survey each month, the probability that your pharmacy will be selected again during the year is 5% or less. Based on the contractor's experience, it is estimated to take less than 30 minutes of non-pharmacist time to assemble and submit the requested information.

It is important to note that all drug purchase price information submitted for this project will remain under the control of CMS, will only be used for the purposes described above, and will remain secure to the extent provided by law, consistent with Exemption 4 of the Freedom of Information Act (FOIA). Accordingly, neither CMS nor Myers and Stauffer will release invoice information and pharmacy identification that is submitted voluntarily and is identified by you as proprietary, except as is required by law.

By participating in the survey, you will have the opportunity to ensure that the market conditions facing your pharmacy are represented in the calculation and evaluation of the NADAC. One of the goals of the NADAC program is to account for the prices that pharmacies pay to acquire drugs.

To accomplish this goal, information from your pharmacy is necessary. Your participation in this endeavor is strongly encouraged and greatly appreciated.

This Retail Price Survey represents an opportunity for Medicaid pharmacies to participate in an initiative to determine a reference price representing the acquisition cost of drugs. Please note that current Federal regulations require State Medicaid programs to consider the professional services performed when setting their dispensing fee rates.

Please contact the Help Desk operated by Myers and Stauffer LC at (855) 457-5264 should you have any questions regarding this survey.

Sincerely,

Barbara Coulter Edwards
Director, Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services

OMB Control #0938-1041

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and CHIP Services

National Average Drug Acquisition Cost (NADAC) Survey Request for Information

March 1, 2013

Your pharmacy has been randomly selected for a sampling of invoices. **We are requesting your pharmacy provide the following information within 14 days**:

1) **Copies** of all wholesaler, distributor, or manufacturer invoices, reflecting all brand, generic and OTC drug purchases transacted with all your wholesale supplier(s) and/or drug manufacturer(s) between

February 1, 2013 through **February 28, 2013**

2) Enclosed Cover Sheet (on gold-colored paper), if identifying submitted information as proprietary and confidential

These records are to be limited to drug ingredient costs only. All costs that are not drug ingredient costs, such as those for shipping, storage, warehousing, or other administrative costs or other internal mark-ups, will not be considered when calculating the NADAC. For purposes of this survey, drug ingredient costs should represent the invoice price paid by your pharmacy to an unrelated third party supplier of outpatient drugs, such as your wholesaler or drug manufacturer. Drug ingredient costs charged to your pharmacy by related parties that also include administrative costs or other mark-ups will not be included in the NADAC calculations. Please do not submit any patient-identifiable information.

Information should be submitted in printed or electronic format and should include the following information:

1) National Drug Code (NDC)
2) Purchase price of drug (drug ingredient cost only – see instructions above)
3) Quantity purchased
4) Purchase date for each product
5) "Item number"-to-NDC crosswalk, if item numbers or other proprietary nomenclature is used on your invoices.

As a time-saving alternative to you or your pharmacy staff submitting invoice records, you may contact your drug supplier(s) to request and authorize them to forward an electronic or hard copy of your purchasing history (as described above) for the requested period directly to Myers and Stauffer LC.
Please do not include any invoices that include Public Health Services 340B drug pricing.

Over →
OMB Control #0938-1041

Information should be mailed, faxed, or sent electronically to the following address within 14 days:

Myers and Stauffer LC

Attention: CMS Pharmacy Survey
9265 Counselors Row, Suite 200
Indianapolis, IN 46240-6419

OR

317-815-5478 FAX

OR

survey@mslcrps.com (Please indicate **"CMS Pharmacy Survey – confidential and proprietary"** in the subject line.)

***** PLEASE USE THE ENCLOSED COVER SHEET (ON GOLD-COLORED PAPER) WHEN SUBMITTING YOUR PHARMACY'S INFORMATION TO IDENTIFY THIS INFORMATION AS PROPRIETARY. FAILURE TO DO SO MAY MEAN IT WILL NOT BE CONSIDERED PROPRIETARY.**

Please be aware that information submitted will not be returned, therefore, please submit copies or electronic files of these records. Your participation in this endeavor is strongly encouraged and greatly appreciated. Please contact the Help Desk operated by Myers and Stauffer LC at (855) 457-5264 should you have any questions.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1041**. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

OMB Control #0938-1041

Center for Medicaid and CHIP Services

COVER SHEET

National Average Drug Acquisition Cost (NADAC)
Survey Request for Information

TO: Myers and Stauffer LC
ATTENTION: CMS Pharmacy Survey

9265 Counselors Row, Suite 200

Indianapolis, IN 46240-6419

OR

317-815-5478 FAX

OR

survey@mslcrps.com
(Please indicate **"CMS Pharmacy Survey – confidential and proprietary"** in the subject line.)

The data contained in this submission is proprietary and confidential financial information that has been submitted voluntarily.

OMB Control #0938-1041

APPENDIX 4: Paperwork Reduction Act Statement

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1041**. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

APPENDIX 5: Sample NADAC Week-to-Week Comparison File

NDC Description	NDC	Old NADAC Per Unit	New NADAC Per Unit	Classification for Rate Setting	Percent Change	Primary Reason
Drug A 5mg Tab	xxxxx-xxxx-xx	0.12345	0.10234	G	-17.10%	Survey Rate
Drug B 5mg Tab	xxxxx-xxxx-xx	6.54321	6.78901	B	3.76%	WAC Adjustment

In the example above, Drug A and Drug B have NADACs in a previous and current NADAC Reference File.

The NADAC for Drug A decreased by 17.10% from the previous NADAC due to results of the monthly pharmacy acquisition cost survey.

The NADAC for Drug B increased by 3.76% from the previous NADAC based upon changes to the Wholesale Acquisition Cost (WAC).

APPENDIX 6: NADAC Week-to-Week Comparison File Data Field Definitions

NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC) WEEK TO WEEK FILE COMPARISON DATA FIELD DEFINITIONS

National Drug Code (NDC) Description:
Identifies the drug name, strength and dosage form of the drug product.

NDC:
The National Drug Code (NDC) is the numerical code maintained by the FDA that includes the labeler code, product code, and package size code. The NDC is an 11-digit code.

Old NADAC Per Unit:
The National Average Drug Acquisition Cost per pricing unit from the previous NADAC Reference File.

New NADAC Per Unit:
The National Average Drug Acquisition Cost per pricing unit from the current NADAC Reference File.

Classification for Rate Setting:
Indicates whether the NDC was considered brand ('B') or generic ('G') for the NADAC rate calculation process. If the NDC was considered brand ('B') and approved under an Abbreviated New Drug Application (ANDA), the indicator is shown as ('B-ANDA').

Percent Change:
The difference between the New NADAC Per Unit and the Old NADAC Per Unit, divided by the Old NADAC Per Unit.

Primary Reason:
Describes the primary reason for the NADAC Per Unit change, see explanation below for each reason:

- Survey Rate: The NADAC Per Unit has been updated using information from the most recently completed pharmacy survey.
- WAC Adjustment: The NADAC Per Unit has been updated to reflect changes in published pricing.
- Help Desk Adjustment: The NADAC Per Unit has been updated as a result of an inquiry to the help desk.

NATIONAL AVERAGE DRUG ACQUISITION COST (NADAC)
WEEK TO WEEK FILE COMPARISON
DATA FIELD DEFINITIONS

- Brand Generic Change: The NADAC Per Unit has been updated as a result of a change in the Classification for Rate Setting.

- Rate Group Change: The NADAC Per Unit has been updated due to placement into a new NADAC drug grouping because of a change in the NDC attributes. NDC attributes that may result in a rate group change include package size updates, brand/generic designation redeterminations and revisions to the active ingredient(s), strength, dosage form or route of administration.

EXHIBIT "C"

S&P CAPITAL IQ
McGRAW HILL FINANCIAL

CONTENTS

Lannett Company, Inc. NYSE:LCI

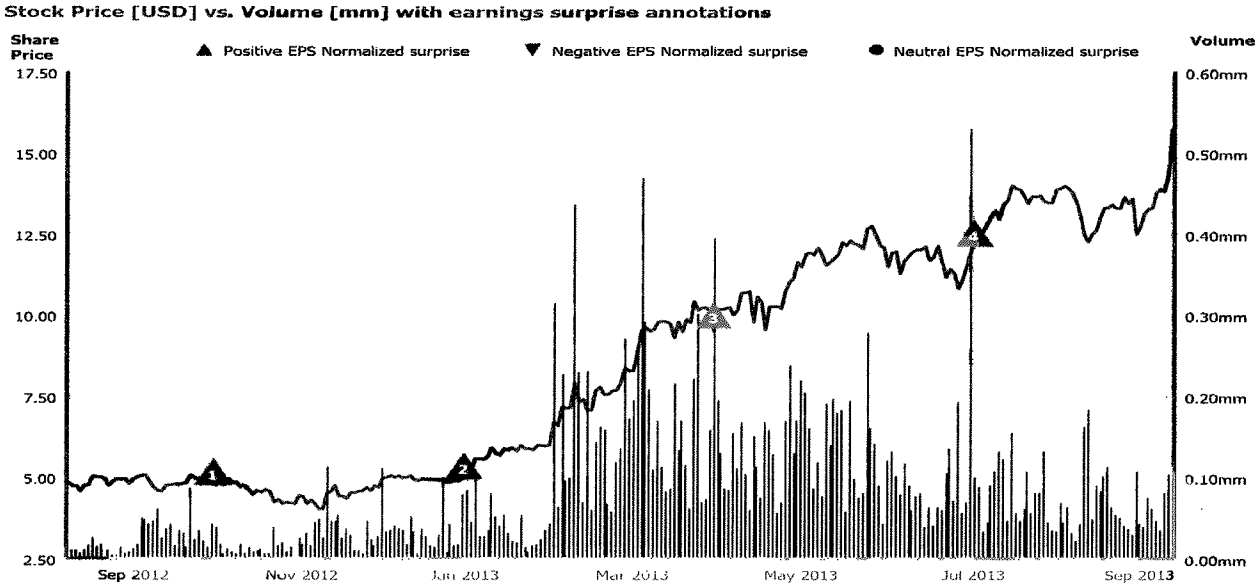
FQ1 2014 Earnings Call Transcripts

Thursday, November 07, 2013 9:30 PM GMT

S&P Capital IQ Estimates

	-FQ1 2014-			-FQ2 2014-	-FY 2014-	-FY 2015-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS Normalized	0.21	0.22	▲4.76	0.14	0.64	0.96
Revenue (mm)	45.02	45.83	▲1.80	53.66	217.12	226.42

Currency: USD
Consensus as of Oct-31-2013 1:20 PM GMT



- EPS NORMALIZED -

	CONSENSUS	ACTUAL	SURPRISE
FQ1 2013	0.04	0.07	▲40.00 %
FQ2 2013	0.08	0.10	▲11.11 %
FQ3 2013	0.13	0.14	▲7.69 %
FQ4 2013	0.07	0.12	▲71.43 %

Call Participants

EXECUTIVES

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Robert Jaffe
Principal and Senior Vice President

ANALYSTS

Dan Duong Trang
Stonegate Capital Partners, Inc., Research Division

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

Presentation

Operator

Welcome to the Lannett Announces Fiscal 2014 First Quarter Financial Results Conference Call. My name is Vanessa, and I will be your operator for today's call. [Operator Instructions] Please note that this conference is being recorded. And I will now turn the call over to Robert Jaffe, Investor Relations for Lannett Company. You may begin.

Robert Jaffe
Principal and Senior Vice President

Thanks, Vanessa. Good afternoon, everyone, and thank you for joining us today to discuss Lannett Company's fiscal 2014 first quarter financial results. On the call today are Arthur Bedrosian, President and CEO; and Marty Galvan, Chief Financial Officer. This call is being broadcast live on the Internet at www.lannett.com. A playback will be available for 3 months and is accessible on Lannett's website.

I would like to make the cautionary statement and remind everyone that all of the information discussed on today's call is covered under the Safe Harbor provisions of the Litigation Reform Act. The company's discussion will include forward-looking information, reflecting management's current forecast of certain aspects of the company's future and actual results could differ materially from those stated or implied.

This afternoon, Arthur will provide a brief overview and Marty will discuss the financial results for the quarter in more detail, followed by Arthur's concluding remarks. We will then open the call for questions. With that said, I will now turn the call over to Arthur Bedrosian. Arthur?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thanks, Robert, and good afternoon, everyone. Today, I have the pleasure of reporting another quarter of record financial results. Our positive momentum continued into our fiscal 2014 first quarter with net sales increasing 30% to $46 million from $35 million in the first quarter of last year, and excluding a charge related to the contract extension with Jerome Stevens Pharmaceuticals, our first quarter adjusted net income of $6.7 million or $0.22 per diluted share was significantly higher than expectations.

The primary drivers for our outstanding first quarter performance was a combination of strong sales of existing products, a favorable product mix and price increases on key products. I'm pleased to report that we believe these positive trends will continue throughout fiscal 2014. Accordingly, we have raised our guidance for fiscal 2014, which Marty will address in more detail shortly. With that brief overview, I'd like now to turn the call over to Marty to review the financials in more detail, then I'll provide an operational update and we'll open the call to questions. Marty?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Thank you, Arthur, and good afternoon, everyone. As Arthur mentioned, we are off to a strong start in fiscal 2014. For our first quarter, net sales rose 30% to $45.8 million from $35.3 million in last year's first quarter. Net sales for our largest product category, thyroid deficiency, grew to $20 million or 44% of our total net sales. Our 2 other largest categories, pain management and cardiovascular, had net sales of $5.2 million and $4.5 million, respectively, representing 11% and 10% of our total net sales, respectively.

As to net sales of our remaining categories: antibiotic was $3.4 million or 7% of total net sales; migraine was $2.7 million or 6%; gout was $2.0 million or 4%; glaucoma was $1.5 million or 3%; gallstone was $1.4 million equal to 3%; obesity was $1.1 million or 2%; and other represented $4.0 million or 10% of our total net sales.

As previously announced, we issued 1.5 million shares of our common stock in connection with the signing of a contract extension with Jerome Stevens Pharmaceuticals to continue as the exclusive distributor in the

United States of 3 of their products. As a result, cost of sales for the fiscal 2014 first quarter included a nonrecurring pretax charge of $20.1 million related to this contract extension.

Continuing with the remainder of the income statement and for completeness and comparative purposes, I will provide both GAAP and adjusted amounts for gross profit, operating income and net income. Gross profit on a GAAP basis was $1.3 million or 3% of net sales.

Excluding the JSP contract renewal charge, gross profit was $21.4 million or 47% of net sales. This compares with last year's first quarter gross profit of $13.6 million or 39% of net sales.

This improvement reflects an 8 percentage point increase. Research and development expenses increased to $4.7 million compared with $3.8 million. Selling, general and administrative expenses increased to $7.2 million compared with $6.2 million in the same quarter of the prior year.

Operating loss reported in accordance with GAAP was $10.6 million for the first quarter of fiscal 2014. Excluding the JSP contract renewal charge, operating income more than doubled to $9.5 million from $3.7 million in the first quarter of fiscal 2013. For the fiscal 2014 first quarter, GAAP to net loss attributable to Lannett Company was $6.0 million or $0.20 per share.

Adjusted net income, which excludes the impact of the JSP contract renewal charge, equal to $12.7 million after tax, was $6.7 million or $0.22 per diluted share. This compares with fiscal 2013 first quarter net income attributable to Lannett Company of $2.9 million or $0.10 per diluted share. Adjusted diluted earnings per share is based on approximately 30.7 million weighted average common shares outstanding.

Last year's first quarter included a favorable pretax litigation settlement of $1.3 million equal to $0.02 per diluted share.

Our balance sheet at September 30, 2013, remained strong with cash, cash equivalents and investment securities of $45.8 million. This amount does not include the $71.5 million of net proceeds related to our stock offering which was completed subsequent to quarter end.

Now turning to our guidance for our fiscal 2014 full year. As Arthur noted, we have raised our guidance for the year due to anticipated strong sales of our existing product portfolio and improved gross profit resulting from favorable sales mix and price increases. It is important to note that our guidance for fiscal 2014 does not include the impact of the Jerome Stevens contract extension, which we expensed in the first quarter of fiscal 2014. With that said, we expect net sales in the range of $245 million to $255 million, up approximately 35% from the previous guidance of $181 million to $186 million.

Gross margin as a percentage of net sales of approximately 57% to 59%, up 15 percentage points from 43% to 44%. R&D expense in the range of $27 million to $29 million, up from $24 million to $26 million in the previous guidance. SG&A expense ranging from $35 million to $37 million, up from $28 million to $30 million. And the full year effective tax rate to be in the range of 36% to 38%, up from the previous guidance of 34% to 36%.

Weighted average common shares outstanding for fiscal 2014 to be approximately 35.4 million, the increase reflecting the impact of the recently completed public offering of 4.3 million shares. Regarding our quarters in fiscal 2014, we expect a significant increase in net sales and EPS in Q2 versus Q1 and anticipate modest sequential growth in net sales and EPS through the remaining quarters.

Capital expenditures in fiscal 2014 are expected to be in the range of $28 million to $32 million, unchanged from previous guidance. The outlook includes $20 million for the purchase and partial fit out related to a new facility. In our last earnings call, we announced that we entered into an agreement to purchase a building in Philadelphia. However, we are currently exploring alternate expansion sites due to an unresolvable issue that arose during our diligence.

With that, I will now turn the call back over to Arthur.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Thank you, Marty. I could not be happier with our financial performance and the progress we have made growing our company. As I've mentioned before, we continue to step up our product development initiatives with products that we believe can generate more revenue and higher margins than we have typically experienced historically. Accordingly, our current pipeline includes 58 product applications pending at the FDA and an additional 58 products in various stages of development, which is a significant increase from just a few months ago. We submitted our first Paragraph IV ANDA filing, which is now past the time for the innovator company to file suit, and additional Paragraph IV candidates are in the later stages of the development.

We continue to wait approval of our oxycodone hydrochloride solution which we expect in the third quarter of fiscal 2014. We continue to lay the groundwork to expand our detailing effort for our C-Topical solution products and are finalizing a contract that will add at least 10 additional sales representatives over the next 2 quarters. We expect to commence our Phase III clinical trial in January, and the target date for our new drug application submission remains December 2014.

Regarding our ANDA for the thalidomide, we have successfully passed both the fast and fed bioequivalence studies and is on track for FDA filing in the third quarter of fiscal 2014. Last month, we successfully closed on a public offering of 5.9 million shares of our common stock. The offering included 4.3 million shares offered by the company with the remaining shares offered by certain selling shareholders of the company. We received net proceeds of approximately $71.5 million and intend to use those net proceeds for potential acquisitions, strategic partnerships and general corporate purposes.

We continue to evaluate several potential acquisition candidates. Our team is looking at products, as well as companies that are a strategic fit and accretive to our business. We're extremely pleased with our first quarter results and excited about the opportunities that lie ahead. We look forward to reporting on our progress and we're grateful to the 345 employees of Lannett Company.
Marty and I would now like to address any questions you may have. Vanessa?

Question and Answer

Operator

[Operator Instructions] And our first question comes from Sumant Kulkarni with Bank of America Merrill Lynch.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

The first one is on your significant top line guidance and please, could you perhaps break that out into how much of that is related to price increase versus some other things?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Increase in the guidance, probably a significant portion is the price increases that we've talked about previously that have now really hit us in a beneficial way.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And how sustainable do you think those are, especially because a large competitor could potentially return on the thyroid product sometime in the calendar first quarter of 2014?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

I believe you're referring to the innovator -- one of the innovator companies. We don't really expect them to return to the market, and if they did, we would expect them to have to put a detailing effort behind that innovator brand name because without it all the products that have been switched to other companies now. So they have to regain that market, I see that as an uphill battle for them quite, frankly. So we're not concerned about remainder of this fiscal year with regards to that product.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And one more before I hop back into the queue. On your growth margins, how sustainable are they beyond the fiscal quarter -- year?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

That's hard to say, but I would believe they are sustainable because we're not expecting any changes that we anticipate at this point. But we're in the commodity business, so it's always hard to determine point when you're going to get additional competition or when prices will erode as they generally do.

Operator

And our next question comes from Steven Crowley with Craig-Hallum.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

In terms of the phenomenon leading up to your price increase or right after your announced price increases, there's a buy-in period in which customers can buy in, at least some of them, at prior prices. I assume given your guidance, most of that's already been reflected and you are now in the new paradigm?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

That's correct. There are a number of contracts that we have with certain customers that they can avail themselves of certain notification about any price increases. That's all been concluded now.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Excellent. Now in terms of some of your efforts in the pain management space. In terms of C-Topical and how it has been performing in the limited number of geographic markets where you've been detailing, can you talk to us about those efforts and how quickly you can bring on this contract sales force and see I guess a positive reaction to those efforts?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, the contract sales organization is actually engaging and hiring people at the moment. So we are moving along on that. We would expect that they'll be fielded on to the marketplace by January. And as far as whether we'll see an uptick, we're starting to find that the marketplace really wants and desires this particular product. A recent organization of ear, nose and throat surgeons actually recommended the use of the product for surgery. So we believe just by merely getting the product into the formulary of those hospitals that discontinued the powder version of this product and letting the surgeons know that the product's available if they want to use it in their practice will bring an uptick in the performance of the sales of this product that will continue. As you recall, our products have been selling well without any really effort on the part of the company to detail it. We have 2 people in a test market. We found the results to be strong enough that we felt that we increased that number to 12 to 20 people that we would see a significant uptick. And our goal now is to get that out here quickly and we are planning to make, even increase the additional 10 to an additional 18 people. So we have the full complement of 20 sales reps in the marketplace this year -- by our fiscal year end, I'm talking about.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

And in terms of your guidance increase, did it include any changed assumptions in the performance the C-Topical at this point? Or if you're going to revise -- I guess, that's the question, were there any positive revisions yet to C-Topical in your guidance change?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, Steve. This is Marty. So, on the guidance, at this stage we have not put in anything significant for that uplift with the detailing effort.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

Okay. And then one more for me. I'll hop back in the queue. In terms of Cody, and its efforts to provide more of your API needs, what can you tell us, Arthur, about progress in objectives as we stand here today?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well, I hate to be -- of course, we're optimistic, let's say that. They will appear to be meeting all their goals and objectives for the fiscal year ending June 30. So I'm expecting to receive 4 additional APIs that we can start to use and they seem to be on track to deliver them. So currently, I think everything is working well there at the moment.

Operator

And our next question comes from Rohit Vanjani with Oppenheimer.

Rohit Vanjani

Oppenheimer & Co. Inc., Research Division

So just a couple of modeling questions. What happened to the amortization of intangibles and product royalties lines? Is that absorbed somewhat?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, we've -- it's in cost of goods sold at the stage. There is only 3 more quarters of it left, but for this fiscal year, we moved it up into that number.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then is there a tax adjustment to the reported $4.242 million because of the JSP agreement?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, there isn't an adjustment. I mean, there is -- we talked about adjusted EPS and GAAP EPS the 4 -- or the negative $4.242 million. That's a GAAP number. So if you want to go to the adjusted number, once you pull out the charge, your adjusted number would be -- the adjusted number would be $3.202 million.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

$3.202 million. Okay, that's what I was after. And then on the price increase for the Digoxin, have you gotten any push back from formularies or anything like that? I mean do you see that, I'm assuming it's a Tier 1 product, is that right?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

It's a Tier what -- say, Tier 1 product?

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Yes, it's preferred tiering or the lowest tiering in a formulary plan because it's a generic. I'm guessing that's probably the case, is that true?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, I wouldn't say -- when you say, "lowest," I'm just not sure we're both understanding the question the right way. The brand products are usually the ones that are preferred by surgeons, let's say, and then everybody reimburses from prescriptions they prefer the generic because they have to pay for it. We still see a tremendous use of generics for this product. We don't see that changing. We do see a decline overall in the market for the Digoxin, brand and generic because the physicians that are prescribing this to new patients, these are the products that continually used on older patients, are those who already been placed on the product. And I'm presuming that because the kind of heart failure that the older people had is not the same that they are experiencing, as you know, they have made a lot of strides in preventing heart attacks. So the decline of the Digoxin in prescription volume continues every year. However, we've been successful in benefiting from the difficulties of our competitors who have left the market and as a result, our market share has continued to grow. We've had a recent price increase on the product as well because we are now only 1 of 2 people in the market. And as a result, I expect that product to do very well. We do believe some of the other competitors may come back into the market. We're anticipating that, but we're not expecting any particular difficulties with the product because they have to face their -- the ASUs and make sure that their products, when they are reintroduced in the market are not going to cause any harm. This is a very serious drug. It's a Narrow Therapeutic Index Drug, and has been allegations again some of those companies with the obese tablets that they have caused the deaths of

some people. So this is a serious drug for these companies to reintroduce. So I believe that the FDA will be scrutinizing those companies very carefully. So I don't see any particular issues in that particular product going forward except a general decline in prescription volume.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

And maybe I didn't ask it right. I was more asking about the -- so I understand everything that you said, and I agree with it. But I was just asking more of the formularies. Have you seen any formulary pushback because of the -- I think it's more than 5x price increase? Have you seen them...

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, you never would because their alternative is to go to the brand and the brand significantly raised their price.

Steven F. Crowley
Craig-Hallum Capital Group LLC, Research Division

I just wanted to make sure that didn't to a worse tiering for you guys because of that pricing.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, no. We're still 50% of the brand price in the marketplace. So the alternative is to use my product or pay more and use the brand. They're still saving a significant amount of money and we have to face the increased cost of doing business that the FDA's going to be expecting from us when those stability studies going in effect the product development and the additional commercial batches. So these price increases that are going on in the industry, I think they're going to stick for all the companies.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Okay. And then the last question for me and this again is on the guidance. Is that reflective -- so are future price increases also reflected in your guidance? Or is it only the price increases that you have right now on Levo and Digoxin that are primarily included in there, along with the quarterly beat that's in there?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes, Rohit. We had some of the price increase on Levo and Digoxin there. They are in the guidance. We've been a little bit on the conservative side in our outlook for the year only because this is the earlier days of the increase, particularly on Digoxin. So there is some of the price increases in the guidance, yes.

Operator

And we have our next question from Scott Henry with Roth Capital Partners.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Just a couple of questions. I apologize, Marty, but could you just give me the pain, cardiovascular and thyroid numbers again. I wanted to make sure I had them correct.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Let me just find that page here. Which one did you want, Scott? I'm sorry.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

The big 3: pain, cardiovascular and thyroid.

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

All right. So pain is $5.2 million; cardiovascular is $4.5 million; and thyroid was $20.0 million.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. I guess the next question, and I don't know if you want to give this granularity or not, but as we look at the revenue guidance, it would seem that it's heavily dependent on thyroid and perhaps cardiovascular. Could you give any color on what can of magnitude, I guess, thyroid is probably a little easier to ballpark given Q1, but how should we think about that cardiovascular section?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Well, cardiovascular, in that section there is 2 products there. First of all, it's the generic Dyazide product which we launched in December of 2011, and the other piece of it is the Digoxin product. So as far as modeling it, it's to decide on the part of the -- on your part to how much the price increase that's out there right now, to what extent it will hold and for how long. But it is the Digoxin price increase that would have a significant impact on the cardiovascular category.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. I think that's certainly fair. And then we would expect some incremental I guess in the thyroid as well, but it seems like Digoxin will be more notable in Q2. It doesn't seem like that had really any affect in Q1, is that fair?

Martin P. Galvan
Chief Financial Officer, Vice President of Finance and Treasurer

Yes.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes, that's fair.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. And I noticed the antibiotic and migraines were trending pretty strong as well. Anything going on there, timing or just simply better trends there?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No. We expect those to continue to grow in the marketplace as well, both of them.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. I guess another kind of strategy question and particularly relevant these days, is that tax rate 36% to 38% is certainly pretty painful to stomach. Any thoughts on ideas to bring that down in the long-term? It certainly takes it's time, but would you look at trying to get assets overseas or different avenues to get that number down?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

We have looked at that. Marty and I interviewed some people that we're very expert in that particular area and we are exploring those possibilities. We understand what we need to do to qualify and it's not something we can resolve right away, unfortunately, certainly not this year. But we are actively looking to do something about that tax rate. It does pain us to know that some of our bigger competitors are paying rates that are 12% to 14% below what we're paying.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. Certainly makes sense something to follow. And just quickly on the pipeline, the Cocaine topical marketing that you were going to do, did I hear you said that, that launch would be in January?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes. Physically the salespeople will be on the road in January and we'll be tracking their progress from January on. The recruiting and the training is all going on now and we've had some success in finding additional information to train them on. Because apparently a recent organization of ear, nose and throat surgeons, I don't have the exact proper name handy, but I can get it to you by email, actually endorsed the use of this product. Not C-Topical, not by brand name but the use of Cocaine topical for ear, nose and throat surgery. And as a result, we expect a lot more physicians looking for information on that. And we're now training the staff to reflect that information. It's a very promising aspect. We didn't expect it and we discovered it when we attended a recent meeting of ear, nose and throat surgeons in October. So this [indiscernible] great drug.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay, great. Okay, I'll look forward to that. And then it looks like the other Cocaine topical trials are on track. The thalidomide, finally, I was juggling some things earlier. Have you filed that product yet?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, that's -- the pass [ph] studies are done. We're assembling the applications as we speak. And it should go in the next quarter.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. So in Q1 or in Q4?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, in our Q -- well, we're past Q1. In our Q3 at the latest. Because of the holidays, we're a little unsure whether we'll get it in by December. So let's say, for sure, Q3 with the agency.

Scott Robert Henry
Roth Capital Partners, LLC, Research Division

Okay. That's helpful. And then I thought I heard you mention that you did submit your first Paragraph IV. Can you give us any comments about the market size for that product, how we should think about that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes, that was around -- it's a little over $200 million in the marketplace. There's 2 other competitors in the market. As we were not sued by the innovator company and the patent holders, so once we get the product approved, we have clear sailing. And -- but that product is with agency now. But it is being reviewed as we speak, because we've already received some comments on it. So we know that application

should get approved. Remember on the GDUFA, they're supposed to do things quickly, and that was a GDUFA application.

Operator

[Operator Instructions] Our next question comes from Dan Trang with Stonegate Securities.

Dan Duong Trang
Stonegate Capital Partners, Inc., Research Division

Regarding the capital raise of $71.5 million, can you give any light as far as breakdown as to what you're going to spend it on or kind of time frame around that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Yes. We were looking -- and continue to talk to 3 potential acquisition candidates. Our concern in the spring, of course, was that if we concluded any one of these transactions, we have to ask then what the cost would be to us and we felt we didn't have enough money to conclude a transaction, especially if any one of the sellers wanted to cash out. And since these were second generation companies, that was a possibility. So as a result, we felt we needed to raise money, so that if they go through with allowing us to acquire them, we wouldn't have the problem of then having to go out to find out the money and maybe not being successful. So having the money handy puts us in a better position to do some or all the acquisitions, presuming all of them are not going to want cash out. But if they did, we estimated we might need $260 million. We only had projected $50 million by June 30. So we have to do something and raising equity was one of the choice -- selling equities, of course, was one of the choices. Now we are closer and discussing one of the transactions a little in more detail, let's say, but again, we're not married yet or engaged. It's a very early stage, but we're hoping one of them will agree to merge with us and let us acquire them. And then we'll start to show you. That's really the bulk of what we wanted that money for. It wasn't for anything else other than really acquisitions that we needed before. We are looking at some product licenses. We made some offers to one of the larger generic competitors that's liquidating about 30 ANDAs. And we've put in a bid there. And that was in the substantial, let's say teens of millions, the offer was. So, we certainly knew that we're going to need money, to acquire licenses, we would need money, to do acquisitions and those were the drivers behind that raise.

Operator

And we now have a follow-up question from Sumant Kulkarni with Bank of America Merrill Lynch.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

What level of new product launch activity have you built into this fiscal year, other than oxycodone?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

We had the anorexia prospects we talked about. We have the cytotoxic drug, we expected around February. We have another product, a pain product that the agency we expected this year and the fifth product escapes my recollection. But we were expecting 5 products to be approved by June 30 of 2014. And in a small degree they're in some of our numbers, but we tend not to make any projections until we get the approvals.

Sumant S. Kulkarni
BofA Merrill Lynch, Research Division

And this is a bigger picture question, all the stars seem to be aligning in a good way for the company, but what keeps you up at night in terms of risks?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

In terms of risks, I'll be frank with you, nothing. I don't see any -- we have so many pokers in the fireplace that any one product or any one thing really is not going to harm this company. Would we be as successful as we are today as we're sitting here today? No, of course not. But we would far and ahead of where we used to be regardless of anything terrible happening. We are cautious. We have a lot of concerns about facilities. We have -- we make sure we're complying with FDA requirements. We always try to stay ahead of those things so that we don't have to worry about them. And quite frankly, those are the things I worry about in that sense. I worry that I'm not ahead of the curve enough when it comes to compliance. We have a lot of government agencies that regulate us and we always try to make sure we are ahead of all of them. And so far, knock wood, we have maintained a very good compliance record. But I worry about never being compliant enough. It's a tough environment we're in, and the FDA is getting very tough on all companies during their normal inspections. Nothing that we can't handle, but it certainly makes me stay on my toes, let's say. But I really have to admit, there is really nothing that we worry about here. The company yes, it's a perfect alignment. A lot of things we've been saying would happen, happened finally. And it's good. And some of them happened, coincidentally, with other good things happening. For example, the company is a strong company, but having price increases on some of our products wasn't anticipated. So certainly that was beneficial to us. But I don't really see anything significant on the horizon that could cause us any pain, quite frankly. We're still conservatively run. We're still careful how we spend money. We still realize we're in a commodity business. While we're enjoying the success of the company, it's not getting to our heads in anyway.

Operator

And we have now up follow-up question from Rohit Vanjani with Oppenheimer.

Rohit Vanjani
Oppenheimer & Co. Inc., Research Division

Along those lines, just had a question on that Form 483 observations. I think you sent the resolutions in mid-August. Have you received the response from the FDA or is there an exit interview expected in near timeline? Or when do you expect the conclusion of that?

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

No, unfortunately, with their furlough -- they were part of the furlough, so they lost a lot of time and this district is very busy. So we don't really know when they're going to come around. We've tried to anticipate that and contact them, but they don't know themselves when they're going to be able to follow up. We do believe our responses were very strong though and there wasn't much room for controversy as we were following up on all agreements we made. So if they were to come in for an exit interview, they'll find everything we told them we're going to do we've undertaken to do or completed already.

Operator

And we have no further questions at this time. I will now turn the call over to Mr. Bedrosian for closing remarks.

Arthur P. Bedrosian
Chief Executive Officer, Director and Chairman of Strategic Planning Committee

Well thank you, again, for joining us today. We're always available to answer further questions and look forward to reporting on our continued progress on our next call. Thank you, everyone.

Operator
And thank you, ladies and gentlemen. This concludes today's conference. Thank you for participating. You may now disconnect.